### Endoscopic Totally Extraperitoneal (TEP) hernia repair for Inguinal Disruption (Sportsman’s hernia): rationale and design of a prospective observational cohort study (TEP-ID-study)

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| Complete List of Authors: | Voorbrood, Charlotte; Diakonessenhuis, Surgery  
Goedhart, Edwin; KNVB / FIFA Medical Centre of Excellence (Sport Medical Centre of the Royal Netherlands Football Association / FIFA Medical Centre of Excellence), SMC  
Verleisdonk, Egbert-Jan; Diakonessenhuis, Surgery  
Sanders, Floris; Diakonessenhuis, Radiology  
Naafs, Dick; Diakonessenhuis, Radiology  
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Endoscopic Totally Extraperitoneal (TEP) hernia repair for Inguinal Disruption (Sportsman’s hernia): rationale and design of a prospective observational cohort study (TEP-ID-study)

C.E.H. Voorbrood¹, E. Goedhart², E.J.M.M. Verleisdonk¹, F. Sanders³, D. Naafs³, J.P.J. Burgmans¹

¹ Department of Surgery; Diakonessenhuis, Utrecht / Zeist, Professor Lorentzlaan 76, Postbus 1002, 3700 BA Zeist
² Department of Radiology, Diakonessenhuis Utrecht / Zeist, Professor Lorentzlaan 76, Postbus 1002, 3700 BA Zeist
³ KNVB / FIFA Medical Centre of Excellence (Sport Medical Centre of the Royal Netherlands Football Association / FIFA Medical Centre of Excellence), Postbus 515, 3700 AM ZEIST

Address correspondence and reprint request to:
Drs. C.E.H. Voorbrood
Department of Surgery; Diakonessenhuis, Zeist, Room: Secretariaat Heelkunde Professor Lorentzlaan 76, 3707 HL Zeist, the Netherlands
cvoorbro@diakhuis.nl
Edwin.Goedhart@KNVB.NL
ejverlei@diakhuis.nl
fsanders@diakhuis.nl
dnaafs@diakhuis.nl
iburgmans@diakhuis.nl
Abstract

Introduction
We describe the rationale and design of an observational cohort study for surgical treatment with the endoscopic Totally Extraperitoneal (TEP) technique in athletes with a painful groin (inguinal disruption).

Methods and analysis
The study is conducted in a high-volume single center hospital, specialized in TEP hernia repair. Patients >18 years with inguinal pain during or after playing sports >3 months without previous inguinal surgery and without benefits from physiotherapy are eligible for inclusion. Patients with another cause of inguinal pain, proved by physical examination, inguinal ultrasound, X-pelvis/hip or MRI, were excluded. Primary outcome is pain after 3 months. Secondary outcomes are pain and resumption of sport (in frequency and intensity).

Discussion
Chronic inguinal pain is a frequent occurring problem in athletes. The diagnosis Inguinal Disruption is made by exclusion of other conditions causing groin pain. Up to now, primary treatment consists of conservative methods. Relevant large and prospective clinical studies on this problem are limited. However recent studies have shown benefits of TEP technique. This study provides a complete assessment of the inguinal area in athletes with chronic inguinal pain before and after treatment by the Totally Extraperitoneal Patch (TEP) technique.

Ethics and dissemination
This study itself is not directly subject of the mentioned Research Grant or any other financial sponsorship. We encourage to publish the results of this research in case of inconclusive or negative findings. All authors gave final approval of the version to be published.

TRIAL REGISTRATION
The study is registered in the Dutch Trial Register (NTR4568).

Keywords: inguinal disruption, sportsman’s hernia, inguinal pain, totally extraperitoneal patch (TEP) technique
**Background**

Inguinal disruption is a condition of chronic inguinal pain in athletes, with an incidence of 0.5-6.2% causing many athletes being affected. Until recently, no consensus regarding nomenclature, diagnosis and treatment was available.

Inguinal disruption is defined as groin pain where no obvious other pathology exists to explain the symptoms. Due to its unclear aetio-pathophysiology and the absence of a typically pattern of complaints, no radiographic study can confirm the diagnosis of inguinal disruption and will lead to deferred treatment. Furthermore, other pathology might be present simultaneously.

Appropriate treatment is important for fast resumption of sport activities of the athlete and is aimed toward its specific pathology. Management of inguinal disruption may start with conservative options (rehabilitation programs, physiotherapy). In case of on-going inguinal pain, surgical repair can be undertaken.

The Totally Extraperitoneal Patch (TEP) technique ensures a comprehensive view to the hernia floor and its insertion area. Moreover, the preperitoneal approach is associated with less chronic postoperative pain and a faster recovery to daily activities. Endoscopic TEP hernia repair with implantation of a polypropylene mesh could therefore, be an appealing technique in athletes with inguinal disruption.

The aim of this manuscript is to describe the rationale and design of a prospective observational cohort study analysing outcomes of Totally Extraperitoneal patch (TEP) hernia repair in athletes with inguinal disruption.
METHODS AND DESIGN

Study design
The study design is an observational, prospective cohort study as this study is designed to assess whether a systematically work-up of athletes with chronic groin pain can select patients that benefit surgical treatment using the TEP technique, involving a high-volume hospital in the Netherlands (Diakonessenhuis Utrecht/Zeist) specialized in the TEP technique for inguinal hernia repair, in collaboration with the Royal Dutch Football Association (Koninklijke Nederlandse Voetbalbond / KNVB).

This study is designed to assess whether surgical treatment using the TEP technique in a selection of athletes with chronic inguinal pain is favourable. Resumption of sport (frequency and intensity) and parameters of pain will be assessed before and 1, 2, 3, 4, 5, 6 weeks and 3 months after surgery, measured by the Numeric Rating Scale (NRS) and the Copenhagen Hip and Groin Outcome Score (HAGOS).\textsuperscript{11,12}

The design, conduct and reporting of this study is adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for observational studies.\textsuperscript{13}

Patient population
Patients older than 18 years with inguinal pain during or after playing sports longer than 3 months without previous inguinal surgery, without benefits from physiotherapy (at least 12 treatments) and a rest period of sports for at least 6 weeks are eligible for inclusion in this study.

Patients with another cause of inguinal pain (proved by physical examination, inguinal ultrasound, X-pelvis/hip or MRI) are excluded.

Intake
Patients are recruited during their first visit at the sport-medical outpatient clinic of the Royal Dutch Football Association (Koninklijke Nederlandse Voetbalbond / KNVB).

Anamnesis focuses on the type of sport, duration of complaints, presence of pain during sport, provoking factors, character of pain particularly on the history of previous surgery as well as on the duration, localisation, character of pain and provoking factors of pain, inguinal swelling, pain at other body areas and the severity of pain. The use of painkillers and its effect is registered. Furthermore, previous history of consultations, imaging and treatments (including the use of painkillers) and the effect is reported.
Physical examination includes inspection and palpation of the inguinal area and examination of sensory changes of the skin.

Functional testing includes range of motion of the hip joint, leg length discrepancy, anterior impingement test and FABERE test (impingement of the hip musculatory), adductor squeeze test, Thomas test (flexibility of the iliopsoas muscle group), and Ely’s test (tightness of rectus femorus).

Supplemental examination is performed, directed at finding abnormalities suggestive for other causes of inguinal pain: painful pubic tubercle on palpation (pubalgia), the test of Carnett (discerning visceral pain from parietal pain in anterior cutaneous nerve entrapment syndrome / ACNES), the test of Lasegue (spinal disc herniation), pain on the hip-adductor insertion (adductor tendinitis) or painful movement of the hip (bursitis iliopectinea, arthrosis).

Additional imaging is performed (ultrasonography, X pelvis/hip and MRI) in all patients.

Inguinal disruption is defined as pain, either of an insidious or acute onset, which occurs predominantly in the groin area near the pubic tubercle where no obvious other pathology, such as a hernia, exists to explain the symptoms.¹

Athletes with chronic inguinal pain diagnosed with inguinal disruption are referred to the Department of Surgery in the Diakonessenhuis Utrecht/Zeist for treatment using the Totally Extraperitoneal Patch technique for inguinal hernia surgery.

**Interventions**

The perioperative care and surgical technique are not different for patients participating in this trial compared to patients who are not. The applied surgical method is the Totally Extraperitoneal Patch technique for inguinal hernia repair, using a mesh implantation technique, performed under general anaesthesia. A 10 x 15 cm, polypropylene monofilament mesh with small pores, weighing 80-85 g/ m² (Prolene, Ethicon, Johnson & Johnson company, Amersfoort, The Netherlands) is used in all patients. There is no consensus regarding the best mesh for endoscopic hernia repair. Recently, we performed a large RCT comparing lightweight Ultrapro and heavyweight Prolene mesh for TEP repair. In the early post-operative period up to 3 months, we did not find any difference in pain, discomfort and quality of life between the two groups¹⁴. Today, the 2-years results have been analyzed and showed significant more pain and higher recurrence rates after Ultrapro mesh. (not published yet) Therefore, we decided to use Prolene. The mesh is positioned in a tension-free manner in the preperitoneal space, as described before.¹⁵ The mesh graft is not fixed, because
fixation could induce pain by nerve entrapment or hematoma. Intra-operative complications and operative time are registered in the Electronic Patient Chart (Dutch: EPD).

Postoperative management

Patients are discharged on the day of surgery and are advised to take analgesics (Paracetamol and, if necessary, Diclofenac), when necessary and to avoid strenuous physical activity (lifting, sports) during the first post-operative week. There are no other (physical) restrictions.

Follow-up

The follow-up of patients is 3 months. The patient will fill in standard forms regarding pain, the use of painkillers and restrictions in movements during activities 1, 2, 3, 4, 5 and 6 weeks postoperatively. Resumption of sport (frequency and intensity) and parameters of pain will be assessed before and 1, 2, 3, 4, 5, 6 weeks and 3 months after surgery. Data is collected using standard forms in Dutch: Sportsmen form, the Numeric Rating Scale (NRS) and the Copenhagen Hip and Groin Outcome Score (HAGOS).\textsuperscript{11,12} Intra-operative data is registered in the Electronic Patient Chart (Dutch: EPD).

After 6 weeks the patients will visit the Surgical Outpatient clinic to investigate possible postoperative complications and the presence of pain. After 3 months the patient will visit the sport-medical outpatient clinic of the Royal Dutch Football Association and will fill in standard forms regarding pain and restrictions in movements during activities again.

Outcomes

The primary outcome is the presence of pain three months after an endoscopic preperitoneal (TEP) hernia correction and consists of a pain score measured by a Numeric Rating Scale (NRS).

Secondary outcomes are pain preoperative and 1, 2, 3, 4, 5 and 6 weeks postoperative, resumption of sport (in frequency and intensity) measured preoperatively and 1, 2, 3, 4, 5, 6 weeks and 3 months postoperative. The NRS is used to assess the amount of experienced pain, where 0 = no pain and 10 = extremely painful. (Dutch version)

Symptoms, pain, restrictions in daily activities, restrictions in sports and groin-related Quality of Life is measured by the Copenhagen Hip and Groin Outcome Score (HAGOS) preoperative, 1 week, 6 weeks and 3 months postoperative.
**Sample size calculation**

Limited data is available regarding pain scores after TEP hernia repair in athletes with inguinal pain. The available data in current literature mainly focusing on whether pain is presence or not, with insufficient data focusing on pain scores. With an estimated decrease in pain scores of at least 50% and with a lost to follow-up of 15%, a sample size of 30 patients was calculated.

**Statistical methods**

Analyses will be performed using SPSS version 17.0 (SPSS, Chicago, Illinois, USA). Descriptive statistics were used for baseline data. Differences in preoperative and postoperative parameters will be analysed by means of a paired sample T-test (parametric data) or a Wilcoxon signed-rank test (non-parametric data). Data will be compared to the reference values in the literature. Significance is set at a level of \( p \leq 0.05 \) (two-sided).

**DISCUSSION**

The study is an observational cohort study designed to assess whether surgical treatment using the Totally Extraperitoneal patch (TEP) technique in athletes with inguinal pain is favourable regarding the presence of postoperative pain. A complete assessment of pain and groin complaints will be performed by filling in standard forms in Dutch: Sportsmen form, the Numeric Rating Scale (NRS) and the Copenhagen Hip and Groin Outcome Score (HAGOS).

In our hospital, the totally extraperitoneal patch technique for inguinal hernia repair is the preferred operative technique, since this technique is associated with less chronic postoperative pain and a faster recovery to daily activities. We aim to maximize participant follow-up by contact at the outpatient clinic and KNVB (after 6 weeks and 3 months) and email contact as a reminder to return the questionnaires.

The strengths of the study is the complete assessment of groin pain with validated questionnaires and standardized physical examination by an experienced hernia surgeon, a specialized sports doctor and a dedicated radiologist. A strict selection of patients is performed to assess favourability of TEP for Inguinal Disruption. A limitation of this study is the absence of a control group with a different operation technique or even a "sham" operation. However, we believe the hypothesis that a weak inguinal floor is a causative factor in the pathophysiology of an Inguinal Disruption and therefore assess the strengthening of this weakened floor by TEP repair. No operation could be ethically reprehensible.
TRIAL STATUS
This study does not fall under the scope of the Medical Research Involving Human Subjects Act (WMO) in accordance with the regional Medical Ethics Committee (VCMO, Nieuwegein, the Netherlands) and the local Ethics Board of the Diakonessenhuis Utrecht/Zeist, the Netherlands. The study is registered in the Dutch Trial Register (NTR4568). Estimated time for including patients will be 1.5 years. Starting at 1st of January 2015. We expect to include 30 patients in total; 2 patients per month during a period of 15 months with a follow up of 3 months.

LIST OF ABBREVIATIONS
ACNES anterior cutaneous nerve entrapment syndrome
EPD Electronic Patient Chart
HAGOS Hip and Groin Outcome Score
KNVB Koninklijke Nederlandse Voetbalbond
NRS Numeric Rating Scale
TEP totally extraperitoneal plasty
STROBE Strengthening the Reporting of Observational Studies in Epidemiology

COMPETING INTERESTS
All authors hereby confirm that a Research Grant has been assigned to the Diakonessenhuis Utrecht/Zeist, or more specifically to the Hernia Centre Zeist, by Johnson & Johnson. This study itself is not directly subject of the above mentioned Research Grant or any other financial sponsorship. Objectivity of data is therefore guaranteed and there is no conflict of interest.
There are no (other) commercial associations that might pose a conflict of interest in connection with the submitted article.

AUTHOR’S CONTRIBUTIONS
CV provided the conception and design of the article and drafted the manuscript. JB conceived the study and have been involved in its design and helped to draft the manuscript. EV, EG, FS and DN have been involved in revising the manuscript critically for important intellectual content. All authors read and gave final approval of the version to be published.
REFERENCES


Editorial comments
1/ Please ensure the manuscript is thoroughly edited, perhaps by a native English-speaking colleague
2/ Clearer statements on ethics and consent are required

Reviewer Name Hannu Paajanen
Institution and Country Department of Surgery
Kuopio University Hospital
Finland
Please state any competing interests or state 'None declared': none declared

Please leave your comments for the authors below
This prospective trial of athlete's groin pain/surgical repair is important. We need more data from various countries and hospitals to understand how to operate longstanding groin pain. I have minor comments:
1. Abstract; line 27. the sentence is incomplete. please revise.
Thank you for underlining the importance of our clinical trial. The sentence is revised.

2. Background, page 3, line 7. ", no radiographic study can confirm.." does not hold true, because in many cases radiological studies are giving the diagnosis, for example incipient inguinal hernia (US), osteitis pubis (MRI), iliopsoas bursitis (MRI)...
Inguinal disruption is an diagnosis per exclusionum when no other pathology exists to explain the symptoms. Other pathology can be shown using radiological studies, as inguinal disruption not.

3. Background, page 3, lines 23,27. The references are wrong in many cases. Please, be more accurate. Ref 8,9 are not related to TEP procedures!
References are revised

4. Materials: page 5, line 38. Why did you select heavy-weight mesh? Agarwal's RCT showed clearly that light-weight mesh in particular for young men is less painful (ref12). I think, you should discuss this more!... and pick up light-weight mesh!
There is no consensus regarding the best mesh for endoscopic hernia repair. Recently, we performed a large RCT comparing lightweight Ultrapro and heavyweight Prolene mesh for TEP repair. In the early post-operative period up to 3 months, we did not find any difference in pain, discomfort and quality of life between the two groups 14. Today, the 2-years results have been analyzed and showed significant more pain and higher recurrence rates after Ultrapro mesh. (not published yet) Therefore, we decided to use Prolene. This is added to the text.

5. Ref 12 is not mentioned in the manuscript!
References are revised

6. Discussion: limitations of the study is lacking. They are at least: no control group or no "sham-operation", surgeon-dependent factors, various meshes to compare, fixation of mesh, others?
The strengths of the study is the complete assessment of groin pain with validated questionnaires and standardized physical examination by an experienced hernia surgeon, a specialized sports...
doctor and a dedicated radiologist. A strict selection of patients is performed to assess favourability of TEP for Inguinal Disruption. A limitation of this study is the absence of a control group with a different operation technique or even a “sham” operation. However, we believe the hypothesis that a weak inguinal floor is a causative factor in the pathophysiology of an Inguinal Disruption and therefore assess the strengthening of this weakened floor by TEP repair. No operation could be ethically reprehensible. This is added to the article.

7. MRI is mandatory preoperatively in every case to find out exact diagnosis!

In accordance with our radiology department we choose a stepwise radiologic assessment of all patients, including an XR as this is a relatively cheap and easy diagnostic tool.

Reviewer Name Mr Aali J Sheen

Institution and Country Central Manchester Foundation trust
Manchester
UK

Please state any competing interests or state ‘None declared’: None declared

Please leave your comments for the authors below

1) I do not fully understand why a pelvic XR is necessary, this is not needed as far as I can see as an MR is carried out

In accordance with our radiology department we choose a stepwise radiologic assessment of all patients, including an XR as this is a relatively cheap and easy diagnostic tool.

2) up to 60 % of patients with the diagnosis of inguinal disruption will have a concomitant pathology and as we already know that the TEP operation has a 70-90% success rate for this condition. Therefore, the exclusion criteria may eliminate many patients that could be included purely because they may have another pathology such as a mild adductor tendinopathy? It will interesting to know if these patients also benefit from repair especially as MR may show changes in tendons that are relatively asymptomatic in patients.

In our protocol we specifically include sportsmen without other pathology. We know that mild complaints (e.g. adductor tendinopathy) will benefit from conservative options. Perhaps in future we might operate on this group of patients as well, thank you for this interesting idea.

3) I would encourage publication of this overview

Thank you.
### STROBE Statement—checklist of items that should be included in reports of observational studies

<table>
<thead>
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<th>Item No</th>
<th>Recommendation</th>
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| **Title and abstract** | 1  
(a) Indicate the study’s design with a commonly used term in the title or the abstract  
(b) Provide in the abstract an informative and balanced summary of what was done and what was found |
| **Introduction** | 2  
Explain the scientific background and rationale for the investigation being reported |
| **Objectives** | 3  
State specific objectives, including any prespecified hypotheses |
| **Methods** | 4  
Present key elements of study design early in the paper |
| **Setting** | 5  
Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection |
| **Participants** | 6  
(a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up  
Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls  
Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants  
(b) Cohort study—For matched studies, give matching criteria and number of exposed and unexposed  
Case-control study—For matched studies, give matching criteria and the number of controls per case |
| **Variables** | 7  
Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable |
| **Data sources/measurement** | 8*  
For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group |
| **Bias** | 9  
Describe any efforts to address potential sources of bias |
| **Study size** | 10  
Explain how the study size was arrived at |
| **Quantitative variables** | 11  
Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why |
| **Statistical methods** | 12  
(a) Describe all statistical methods, including those used to control for confounding  
(b) Describe any methods used to examine subgroups and interactions  
(c) Explain how missing data were addressed  
(d) Cohort study—If applicable, explain how loss to follow-up was addressed  
Case-control study—If applicable, explain how matching of cases and controls was addressed  
Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy  
(e) Describe any sensitivity analyses |

Continued on next page
Results

Participants 13*
(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
(b) Give reasons for non-participation at each stage
(c) Consider use of a flow diagram

Descriptive data 14*
(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
(b) Indicate number of participants with missing data for each variable of interest
(c) Cohort study—Summarise follow-up time (eg, average and total amount)

Outcome data 15*
Cohort study—Report numbers of outcome events or summary measures over time
Case-control study—Report numbers in each exposure category, or summary measures of exposure
Cross-sectional study—Report numbers of outcome events or summary measures

Main results 16
(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
(b) Report category boundaries when continuous variables were categorized
(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period

Other analyses 17
Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses

Discussion

Key results 18
Summarise key results with reference to study objectives

Limitations 19
Discuss limitations of the study, taking into account sources of potential bias or imprecision.
Discuss both direction and magnitude of any potential bias

Interpretation 20
Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence

Generalisability 21
Discuss the generalisability (external validity) of the study results

Other information

Funding 22
Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

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¹ Department of Surgery; Diakonessenhuis, Utrecht / Zeist, Professor Lorentzlaan 76, Postbus 1002, 3700 BA Zeist
² Department of Radiology, Diakonessenhuis Utrecht / Zeist, Professor Lorentzlaan 76, Postbus 1002, 3700 BA Zeist
³ KNVB / FIFA Medical Centre of Excellence (Sport Medical Centre of the Royal Netherlands Football Association / FIFA Medical Centre of Excellence), Postbus 515, 3700 AM ZEIST

Address correspondence and reprint request to:
Drs. C.E.H. Voorbrood
Department of Surgery; Diakonessenhuis, Zeist, Room: Secretariaat Heelkunde Professor Lorentzlaan 76, 3707 HL Zeist, the Netherlands
cvoorbro@diakhuis.nl
Edwin.Goedhart@KNVB.NL
ejverlei@diakhuis.nl
fsanders@diakhuis.nl
daafs@diakhuis.nl
iburgmans@diakhuis.nl
Abstract

Introduction

Chronic inguinal pain is a frequently occurring problem in athletes. A diagnosis of Inguinal Disruption is made by exclusion of other conditions causing groin pain. Up to now, conservative medical management is considered to be the primary treatment for this condition. Relevant large and prospective clinical studies regarding the treatment of inguinal disruption are limited, however, recent studies have shown the benefits of the TEP technique.

This study provides a complete assessment of the inguinal area in athletes with chronic inguinal pain before and after treatment with the Totally Extraperitoneal Patch (TEP) technique.

Methods and analysis

We describe the rationale and design of an observational cohort study for surgical treatment with the endoscopic Totally Extraperitoneal (TEP) technique in athletes with a painful groin (inguinal disruption).

The study is being conducted in a high-volume, single center hospital, specialized in TEP hernia repair. Patients over 18 years, suffering from inguinal pain, for at least 3 months, during or after playing sports and whom have not undergone previous inguinal surgery and have received no benefit from physiotherapy are eligible for inclusion. Patients with another cause of inguinal pain, proven by physical examination, inguinal ultrasound, X-pelvis / hip or MRI, are excluded.

Primary outcome is reduction in pain after 3 months. Secondary outcomes are pain reduction, physical functioning and resumption of sport (in frequency and intensity).

Ethics and dissemination

An unrestricted research grant for general study purposes was assigned to the Hernia Centre. This study itself is not directly subject to the above mentioned research grant or any other financial sponsorship. We intend to publish the outcome of the study, regardless of the findings. All authors will give final approval of the manuscript version to be published.

Keywords: inguinal disruption, sportsman’s hernia, inguinal pain, totally extraperitoneal patch (TEP) technique
Strengths and limitations of this study
The strengths of the study are the complete assessment of groin pain with validated questionnaires and standardized physical examination by an experienced hernia surgeon, a specialized sports doctor and a dedicated radiologist. A strict selection of patients is performed to assess the favourability of Totally Extraperitoneal Patch (TEP) technique for inguinal disruption. A limitation of this study is the absence of a control group with a different operation technique or even a "sham" operation. However, in light of our hypothesis, we believe that not carrying out a operation (sham) would be morally unethical. We hypothesize that a weak inguinal floor may be a causative or contributory factor in the pathophysiology of an inguinal disruption and that strengthening this weakened floor with a TEP repair may be of benefit to patients with this condition.

Background
Inguinal disruption is a condition of chronic inguinal pain in athletes, with an incidence of 0.5-6.2%. Until recently, no consensus regarding nomenclature, diagnosis and treatment was available. Inguinal disruption is defined as groin pain where no other obvious pathology exists to explain the symptoms. Due to its unclear aetio-pathophysiology and the absence of a typical pattern of complaints, no radiographic study can confirm the diagnosis of inguinal disruption and will lead to deferred treatment. Furthermore, other pathology might be present simultaneously.

Appropriate treatment is important for fast resumption of sport activities of the athlete and is aimed toward its specific pathology. Management of inguinal disruption may start with conservative options (rehabilitation programs, physiotherapy). Surgical repair may be necessary in patients with continuous inguinal pain.

The Totally Extraperitoneal Patch (TEP) technique ensures a comprehensive view of the hernia floor. Moreover, the preperitoneal approach is associated with less chronic postoperative pain and a faster recovery in daily activities. Endoscopic TEP hernia repair with implantation of a polypropylene mesh could therefore, be an appealing technique for athletes with inguinal disruption.
The aim of this manuscript is to describe the rationale and design of a prospective observational cohort study analysing outcomes of Totally Extraperitoneal patch (TEP) hernia repair in athletes with inguinal disruption.

METHODS AND DESIGN

Study design
The study design is an observational, prospective cohort study. The study is designed to assess whether a systemic work-up of athletes with chronic groin pain can select patients would most benefit from surgical treatment using the TEP technique. A high-volume hospital in the Netherlands (Diakonessenhuis Utrecht/Zeist), specialized in the TEP technique for inguinal hernia repair, will carry out the study in collaboration with the Royal Dutch Football Association (Koninklijke Nederlandse Voetbalbond / KNVB). Resumption of sport (frequency and intensity) and pain parameters will be assessed preoperatively and at 1, 2, 3, 4, 5, 6 weeks and 12 weeks after surgery, measured by the Numeric Rating Scale (NRS) and the Copenhagen Hip and Groin Outcome Score (HAGOS).11,12

Patient population
Patients over 18 years, suffering from inguinal pain, for at least 3 months, during or after playing sports and whom have not undergone previous inguinal surgery and have received no benefit from physiotherapy (at least 12 treatments) and who have undergone a rest period from sports of at least 6 weeks are eligible for inclusion in this study. Patients with another cause of inguinal pain (proved by physical examination, inguinal ultrasound, X-pelvis/hip or MRI) are excluded.

Intake
Patients are recruited during their first visit to the sport-medical outpatient clinic of the Royal Dutch Football Association (Koninklijke Nederlandse Voetbalbond, KNVB). Informed consent is obtained during this visit. Anamnesis, functional testing and supplemental examination is performed at the sport-medical outpatient clinic of the KNVB.

Anamnesis focuses on the type of sport, duration of complaints, presence of pain during sport, provoking factors, character and severity of the pain, history of previous surgery as well as on the duration, localisation, character of pain and provoking factors of pain, inguinal swelling, pain in other body areas and physical limitations. The use of pain medication and its...
effect is registered. Furthermore, previous history of consultations, imaging and treatments (including the use of pain medication) and their effect is reported.

Physical examination includes inspection and palpation of the inguinal area and examination of sensory changes of the skin.

Functional testing includes range of motion of the hip joint, leg length discrepancy, anterior impingement test and FABERE test (impingement of the hip musculature), adductor squeeze test, Thomas test (flexibility of the iliopsoas muscle group), and Ely’s test (tightness of rectus femoris).\textsuperscript{13,14,15}

Supplemental examination is performed, directed at finding abnormalities suggestive for other causes of inguinal pain: painful pubic tubercle on palpation (pubalgia), the test of Carnett (discerning visceral pain from parietal pain in anterior cutaneous nerve entrapment syndrome / ACNES), the test of Lasegue (spinal disc herniation), pain on the hip-adductor insertion (adductor tendinitis) or painful movement of the hip (bursitis iliopectinea, arthrosis).

In case of inguinal disruption, patients are recruited for the study and informed consent is obtained.

Inguinal disruption is defined as pain, either of a gradual or acute onset, which occurs predominantly in the groin area near the pubic tubercle and where no other obvious pathology, such as a hernia, exists to explain the symptoms.\textsuperscript{1}

Athletes with chronic inguinal pain and diagnosed with inguinal disruption are referred to the Department of Surgery in the Diakonessenhuis Utrecht/Zeist. Physical examination is repeated and additional imaging is performed (ultrasonography, X pelvis/hip and MRI) in all patients. After exclusion of an inguinal hernia and other causes of groin pain, patients are planned for treatment using the TEP technique for inguinal hernia surgery.

All data is collected using standard forms in Dutch: a self-designed Sportsmen form, the Numeric Rating Scale and the Copenhagen Hip and Groin Outcome Score (HAGOS).\textsuperscript{11,12}

The patient will fill in these standard forms assessing pain, the use of pain medication and restrictions in movements during activities preoperatively and at 1, 2, 3, 4, 5 and 6 weeks postoperatively. Resumption of sport (frequency and intensity) and parameters of pain will be assessed preoperatively and at 1, 2, 3, 4, 5, 6 and 12 weeks after surgery.

\textit{Interventions}

The perioperative care and surgical technique is standard for all patients undergoing this procedure and does not differ for patients participating in this study. The applied surgical method is the Totally Extraperitoneal Patch technique for inguinal hernia repair, using a
mesh implantation technique, performed under general anaesthesia. A 10 x 15 cm, polypropylene monofilament mesh with small pores, weighing 80-85 g/ m² (Prolene, Ethicon, Johnson & Johnson company, Amersfoort, The Netherlands) is used in all patients. There is no consensus regarding the best mesh for endoscopic hernia repair. Recently, we performed a large RCT comparing lightweight Ultrapro and heavyweight Prolene mesh for TEP repair. In the early post-operative period up to 3 months, we did not find any difference in pain, discomfort and quality of life between the two groups\textsuperscript{16}. The 2-year results have been analyzed and showed significantly higher pain scores and higher hernia recurrence rates after Ultrapro mesh. (unpublished results) Due to the results of our previous findings, we decided to use Prolene in this study. The mesh is positioned in a tension-free manner in the preperitoneal space, as previously described.\textsuperscript{17} The mesh graft is not fixed, as fixation may induce pain due to nerve entrapment or haematoma. Intra-operative complications and operative time are registered in the Electronic Patient Chart (Dutch: EPD).

Postoperative management

Patients are discharged on the day of surgery and are advised to take analgesics (Paracetamol and, if necessary, Diclofenac), according to need and to avoid strenuous physical activity (lifting, sports) during the first post-operative week. There are no other (physical) restrictions.

Follow-up

The follow-up of patients is 3 months. The patient will fill in standard forms assessing pain scores, the use of pain medication and its effect and restrictions in movements during activities preoperatively and 1, 2, 3, 4, 5 and 6 weeks postoperatively. Resumption of sport (frequency and intensity) and pain parameters will be assessed preoperatively and 1, 2, 3, 4, 5, 6 weeks and 12 weeks after surgery. Data is collected using standard forms in Dutch: Sportsmen form, the Numeric Rating Scale (NRS) and the Copenhagen Hip and Groin Outcome Score (HAGOS).\textsuperscript{11,12} Intra-operative data is registered in the Electronic Patient Chart (Dutch: EPD).

After 6 weeks the patients will visit the Surgical Outpatient clinic to assess pain parameters and possible postoperative complications. After 3 months, the patient will visit the sport-medical outpatient clinic of the Royal Dutch Football Association and will again fill in the same standard forms assessing pain and restrictions in movements during activities.
Outcomes

The primary outcome is the presence of pain three months after an endoscopic preperitoneal (TEP) hernia correction and consists of a pain score measured by a Numeric Rating Scale (NRS).

Secondary outcomes are:

- Pain scores measured in rest and during activity preoperatively and at 1, 2, 3, 4, 5 and 6 weeks postoperatively, using the NRS scale, where 0 = no pain and 10 = extremely painful (Dutch version).
- Resumption of sport (in frequency and intensity) measured preoperatively and at 1, 2, 3, 4, 5, 6 weeks and 12 weeks postoperatively.
- Quality of Life is measured by the Copenhagen Hip and Groin Outcome Score (HAGOS) preoperatively, 1 week, 6 weeks and 12 weeks postoperatively.

Sample size calculation

Limited data is available regarding pain scores after TEP hernia repair in athletes with inguinal pain. A study of Dojcinovic et al\(^5\) shows that patients who underwent surgery for chronic groin pain unresponsive to conservative options had benefits from surgery. Pain scores measured by a Visual Analogue Scale were 6.49 preoperatively and 0.54 12 weeks postoperatively. Based on a Cohen’s effect size of 0.5 with a type 1 error, a significance level of \(\alpha= 0.05\) and a power of 80%, the calculated sample size is 32 patients.

Statistical methods

Analyses will be performed using SPSS version 17.0 (SPSS, Chicago, Illinois, USA). Descriptive statistics were used for baseline data. Differences in preoperative and postoperative parameters will be analysed by means of a paired sample T-test (parametric data) or a Wilcoxon signed-ranked test (non-parametric data). Data will be compared to the reference values in the literature. Significance is set at a level of \(p \leq 0.05\) (two-sided).

STATUS

This study does not fall under the scope of the Medical Research Involving Human Subjects Act (WMO) in accordance with the regional Medical Ethics Committee (VCMO, Nieuwegein, the Netherlands) and the local Ethics Board of the Diakonessenhuis Utrecht/Zeist, the Netherlands. Estimated inclusion is 18 months beginning on the 1st of January 2015. We expect to include 32 patients in total; 2 patients per month during a period of 15 months with a follow up of 3 months.
LIST OF ABBREVIATIONS
ACNES: Anterior Cutaneous Nerve Entrapment Syndrome
EPD: Electronic Patient Chart
HAGOS: Hip And Groin Outcome Score
KNVB: Koninklijke Nederlandse VoetbalBond
NRS: Numeric Rating Scale
TEP: Totally Extraperitoneal Patch

COMPETING INTERESTS
All authors hereby confirm that an unrestricted Research Grant has been assigned to Diakonessenhuis Utrecht/Zeist, or more specifically to the Hernia Centre Zeist, by Johnson & Johnson. This physician-initiated study itself is not directly subject to the above mentioned Research Grant or any other financial sponsorship. Objectivity of the data is therefore guaranteed.

AUTHOR’S CONTRIBUTIONS
CV provided the conception and design of the article and drafted the manuscript. JB conceived the study and has been involved in its design and helped to draft the manuscript. EV, EG, FS and DN have been involved in revising the manuscript critically for important intellectual content. All authors read and gave final approval of the version to be published.

REFERENCES


ADDENDUM

Sportsmen form (in Dutch)

Numeric Rating Scale (NRS, in Dutch)

Copenhagen Hip and Groin Outcome Score (HAGOS, in Dutch).
Endoscopic totally extraperitoneal (TEP) hernia repair for inguinal disruption (Sportsman's hernia): rationale and design of a prospective observational cohort study (TEP-ID-study)

C E H Voorbrood, E Goedhart, E J M M Verleisdonk, F Sanders, D Naafs and J P J Burgmans

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