Continuous and interrupted abdominal-wall closure after primary emergency midline laparotomy (CONIAC-trial): study protocol for a randomised controlled single centre trial

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ABSTRACT

Introduction The optimal closure of the abdominal wall after emergency midline laparotomy is still a matter of debate due to lack of evidence. Although closure of the fascia using a continuous, all-layer suture technique with slowly absorbable monofilament material is common, complications like burst abdomen and hernia are frequent.

Methods and analysis This randomised controlled trial with a 1:1 allocation evaluates the efficacy and safety of a continuous suture with or without additional interrupted retention sutures for closure of the abdominal fascia. Patients with an indication for a primary emergency midline laparotomy are eligible to participate in this study and will be randomised intraoperatively via block randomisation. Fascia closure in the intervention group will be done with a standard continuous suture with slowly absorbable monofilament material (MonoMax 1, B. Braun, Tuttlingen, Germany) and additional interrupted retention sutures every 2 cm of the fascia using rapidly absorbable braided material (Vicryl 2, Ethicon, Norderstedt, Germany). In the control group, the fascia is closed only with the standard continuous suture with slowly absorbable monofilament material. Sample size calculations (n=111 per study arm) are based on the available literature. The primary endpoint is the rate of dehiscence of the abdominal fascia (rate of burst abdomen within 30 days or rate of incisional hernia within 12 months). Secondary endpoints are wound infections, quality of life, length of hospital stay, morbidity and mortality. Patients as well as individuals involved in data collection, endpoint assessment, data analysis and quality of life assessment will be blinded.

Ethics and dissemination The study protocol, the patient information and the informed consent form have been approved by the ethics committee of the Ludwig-Maximilians-University, Munich, Germany (reference number: 20-1041). Study findings will be submitted for publication in peer-reviewed journals.

Trial registration number DRKS00024802.

WHO universal trial number U1111-1259-1956

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This trial may lead to further evidence for the optimal closure technique of emergency midline laparotomies.
⇒ The prospective, randomised design of the trial with a 1:1 allocation will reduce potential bias.
⇒ The inclusion of patients undergoing primary midline laparotomy only for an emergency indication, will lead to a homogeneous study population.
⇒ The use of the SF-36-Health-Survey and Wound-Quality of Life questionnaire will increase measurement precision for core quality of life domains.
⇒ This trial compares only two specific methods for fascial closure and does not compare other techniques and suturing materials.

INTRODUCTION

In Germany, more than 700,000 laparotomies are performed annually. The most common late complications after laparotomy because of fascia dehiscence are incisional hernias. The incidence of incisional hernias 1 year after surgery is around 9%–20%, but can rise up to over 35% in patients with risk factors. This represents a major health and social problem. An incisional hernia is often associated with pain and limitations in professional life. Although agreement in choice of treatment strategy for patients with incisional hernias among surgeons is low, these hernias often require surgical treatment with corresponding perioperative risks. An early postoperative fascia dehiscence leads to the formation of a burst abdomen. The rate of reoperation due to a burst abdomen is 1%–3% according to the literature. Many studies have been conducted over the last few years to find the best method for abdominal wall closure after laparotomies. Thus, there are a lot of trials comparing a continuous...
with a interrupted suturing technique, fast with slowly absorbable suture material and small (ratio of suture to wound length of at least 4/1) with large stitch spacing of the suture method.

The guideline of the European Hernia Society recommends a continuous suture with a slowly absorbable monofilament thread in the ‘small bites’ technique (stitch distance to fascia edge 5–8mm, distance between stitches 5 mm) with a ratio of suture to wound length of at least 4/1 for the closure of elective midline laparotomies.7

There is strong evidence for this technique to prevent incisional hernias—the slowly superior the fast absorbable suture materials and the ‘small bites’ the ‘large bites’ technique.19

For the closure of laparotomies in emergency procedures, which are associated with an increased risk of wound dehiscence, burst abdomen and as result also incisional hernia,19 no recommendation for a special suturing technique can be made due to a lack of evidence.7 The frequency of fascia dehiscence correlates with several risk factors, for example, hypoalbuminaemia, anaemia, malnutrition, chronic lung diseases or postoperative vomiting and ileus.10 11 In these cases, some studies recommend the use of additional retention sutures to reduce tension on the fascia suture and thus allow a better healing. Such a technique can reduce the rate of burst abdomen and hernias12 and their use has also been suggested as a treatment choice for managing fascial dehiscence.13 14 However, the guideline of the European Hernia Society does not make a recommendation for routine use of this fascia closure technique due to a lack of evidence.7 In addition, these sutures are associated with increased pain, postoperative discomfort, skin maceration and wound complications, as they pass through the entire abdominal wall, that is, fascia, subcutaneous fat and skin.15 Due to this, routine application of this technique has not been well accepted. Nevertheless, that prophylactic retention sutures could be an option in high-risk patients with multiple risk factors for preventing fascia dehiscence without imposing remarkable postoperative complications.15 The negative side effects could be reduced by performing subcutaneous retention sutures without involving the skin.16

However, prospective data are lacking.

Rationale for this randomised trial

There is still lack of evidence for the optimal closure technique for emergency midline laparotomies. The continuous suture technique in combination with intermediate sutures could reduce the increased rate of fascial dehiscence in the emergency setting. To avoid the increased pain of penetrating retention sutures, these sutures should only be stitched through the abdominal wall fascia. However, it is not yet clear whether this suture technique is superior to continuous suturing alone in the emergency situation and does not lead to more wound complications. This should be analysed in this randomised trial.

METHODS

Trial design and study population

The CONIAC (continuous and interrupted abdominal-wall closure after primary emergency midline laparotomy) trial is a single-centre, randomised controlled superiority trial featuring a two-arm parallel group design with a 1:1 allocation ratio. The flow chart of the study is shown in figure 1. Patients who require a primary emergency operation via midline laparotomy due to an acute disease of the abdominal visceral organs are screened for inclusion. Participants will be randomised either to the intervention or the control group.

Informed consent

Each patient included in the study must be able to provide written informed consent prior to participation (see online supplemental file 1, patient consent form). Due to the emergency situation, the informed consent takes place shortly before the visceral surgical procedure and will be carried out by the staff surgeons of the University Hospital Augsburg. This procedure was approved by the local ethics committee.

Eligibility criteria

Patients who need to undergo a primary emergency operation via midline laparotomy must be at least 18 years old with a survival expectancy of at least 12 months to be eligible to participate in the study.

Exclusion criteria

Incapacitated patients, underage patients, pregnant patients and patients with immune system impairments, serious psychiatric disorders and lack of compliance are excluded from the study participation. Other exclusion criteria are a lack of understanding (linguistic or cognitive) for study instructions, chemotherapy or radiotherapy up to 2 months before surgery, and an existing midline laparotomy (excluding condition after laparoscopic surgery, cholecystectomy, hysterectomy and section, transverse laparotomy). In addition to these preoperative criteria, the septic source must be successfully controlled and in case of peritonitis abdominal lavage must be performed prior to intraoperative randomisation.

Secondary exclusion criteria and adverse events

Patients who must undergo a relaparotomy within 30 days after the primary operation via midline laparotomy or die within this period will be secondarily excluded from the study. Any adverse event (AE) or unintended effect of the trial interventions will be documented and assessed.

Data assessment and study plan

Patients’ demographic data, intraoperative findings, the cause for operation and the associated surgical treatment will be documented. In addition, the length of skin and fascia incision will be captured.

There will be six visits within the whole trial (table 1). There will be two visits during the hospital stay, on day 2±1 postoperatively (visit 3) and on the day of discharge.
(visit 4). On these visits data on postoperative complications (according to the Clavien-Dindo classification\textsuperscript{17}), length of hospital stay, pulmonary complications and especially on wound healing disorders, in order to record burst abdomen, is collected.

Follow-up visits are carried out on day 30 after surgery (visit 5) and 12 months after surgery (visit 6). On these visits, besides clinical examination of the abdominal wall, an ultrasound will be performed to assess the primary endpoint. Quality of life is assessed using a validated questionnaire (Short Form (SF)-36 V.1.1 Health Survey\textsuperscript{18}), which has previously been used in trials on surgical interventions. Furthermore, the Wound-Quality of Life questionnaire\textsuperscript{19} will be used to assess how patients’ cope with their wounds.

Endpoints
The primary endpoint of the CONIAC trial is the incidence of postoperative fascia dehiscence, defined as a burst abdomen within 30 days or an incisional hernia within 12 months after operation.

A burst abdomen is present if there is a gap in the continuity of the abdominal fascia (assessed either by clinical or radiologic diagnostics) with a wound dehiscence and/or a consecutive relapse operation occurring up to day 30 after surgery.

Incisional hernias will be assessed in the 12 months visit either by examination of an experienced surgeon and ultrasound of the abdominal wall by an experienced radiologist in the study centre. Therefore, the surgeon must be experienced in abdominal wall examination and must not be involved in the treatment or operation of the patient. An incisional hernia is defined as a protruding sac of the abdominal cavity through the fascia in the ultrasound and must be confirmed by clinical examination.

There will be several surgical and non-surgical parameters assessed as secondary endpoints as shown in table 2.

Surgical procedures and trial intervention
There will be a standardised treatment of the operated patients except to the closure of the abdominal wall, which will be performed according to the study protocol. All patients receive perioperative antibiotic prophylaxis according to local standards or antibiotic therapy depending on clinical situation. The skin and subcutaneous tissue will be cut by electric cautery, the fascia and peritoneum will be opened using scissors. The intra-abdominal surgical interventions will be performed according to the underlying disease in a standardised way independently to study enrolment. If there is a septic focus, intra-abdominal swabs for microbiological diagnostics, abdominal lavage and the placement of intra-abdominal drains will be made. Furthermore, the antibiotic treatment will be continued and adjusted according to the swab results.

Before closing the abdominal wall, eligible patients will be randomised in the two treatment groups. In the intervention group the abdominal fascia will be closed using...
a running suture in combination with interrupted retention sutures. The continues suture will be performed as a suture of the abdominal fascia with two slowly absorbable, monofilament MonoMax loops (B. Braun, Tuttlingen, Germany). Therefore, a ‘small bites’ suturing technique in an at least suture to wound length ratio of 4/1 will be used. The first stitches of the two loops will be made cranial and caudal of the fascia incision. After closing half of the length of the wound, the needle will be cut of both strings, one of the loop strings threated in the last loop of the suture and then both ends tied together with at least four counterrotating knots. There is no additional dissection of the fascia for placing the retention sutures.

In the control group, the fascia is closed only with the two MonoMax 1 loops as described above. The subcutaneous tissue is not sutured and no subcutaneous drainage is used. The skin will be closed with clips and the skin and thus the fascia incision will be measured.

**Assessment of safety**

Safety of patients will be primarily assessed with annual safety reports (ASR) according to the declaration of Good Clinical Practice § 13, passage 6. As part of the ASR, adverse and serious AE will be recorded. To maintain patient safety, there will be clinical and ultrasound examinations of the abdominal wall 30 days and 12 months after operation. To detect long-range AEs, the secondary endpoints wound infection, wound pain, suture granuloma, mortality, reoperation, quality of life and duration of hospital stay will be assessed.

**Randomisation and blinding**

Participants will be randomised intraoperatively before closure of the abdominal wall with sealed, opaque envelopes. Block randomisation will be performed with randomisation numbers allocated to the two groups in balanced permuted blocks to ensure equal-sized groups. The size

**Table 1** Studyplan CONIAC (continuous and interrupted abdominal-wall closure after primary emergency midline laparotomy) trial

<table>
<thead>
<tr>
<th>Visit 1 (Screening/preoperative)</th>
<th>Visit 2 (day 0)</th>
<th>Visit 3 (day 2±1)</th>
<th>Visit 4 (day of discharge)</th>
<th>Visit 5 (day 30±5)</th>
<th>Visit 6 (month 12±1 postsurgery)</th>
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<tbody>
<tr>
<td>Informed consent</td>
<td>x</td>
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<td>x</td>
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<td>Demographic data</td>
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<tr>
<td>Inclusion/exclusion</td>
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<tr>
<td>Medical history</td>
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<td>Reason for surgery</td>
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<td>Physical examination</td>
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<td>Surgery</td>
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<td>Abdominal AE/SAE</td>
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<tr>
<td>Ultrasound abdomen</td>
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<td>Burst abdomen</td>
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<td>Wound infection</td>
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<tr>
<td>Incisional hernia</td>
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<tr>
<td>Quality of life (SF (Short Form)-36, wound questionnaire)</td>
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<td>x</td>
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<tr>
<td>Discharge</td>
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</tbody>
</table>

AE, adverse event; SAE, serious adverse event.
of the individual blocks will only be disclosed after the study has been completed so as not to allow prediction of group allocation. A sufficient number of subjects will be recruited according to the sample size calculation to minimise random errors and to ensure sufficient power to test the hypothesis of the primary endpoint. Randomisation will be performed by individuals not involved in the surgical procedure, data evaluation, data analysis, postoperative care and follow-up of the patients. When the study is finished, all unopened envelopes will be compared with the allocated randomisation numbers and checked for completeness.

Patients as well as individuals involved in data collection, endpoint assessment, data analysis and quality of life assessment will be blinded. Participating surgeons will be instructed which treatment procedures. Blinding of surgeons is not feasible due to the nature of the interventions. To reduce bias, these surgeons are not involved in data collection or analysis. Nurses and doctors assessing the endpoints on the ward are blinded.

**Sample size calculation**

The sample size calculation is based on the primary endpoint 'postoperative fascia dehiscence'. In this respect, the incidence of burst abdomen and incisional hernia after emergency midline laparotomy is conservatively esteemed around 23% in literature. Only few studies evaluated the effect of additional retention sutures. A prospective, randomised trial found lower rates of fascia dehiscence and incisional hernia in the group with additional sutures (n=8/147 (5.4%)) compared with a running suture alone (n=24/148 (16%)), which correlates with a reduction of 65%. Based on these findings, a sample size of 101 patients per treatment group is required to ensure a power of 80% at a two-sided significance level of 5%. To compensate potential drop-outs, a rate of 10% was added to each treatment group. This leads to a total number of 222 patients to be enrolled, respectively, 111 patients per treatment group.

**Data collection**

All data will be documented in standardised hard copy case report forms (CRFs). The completed CRFs will be reviewed by one of the investigators or an authorised subinvestigator. All data collected according to the study protocol will be manually transferred from the CRFs to an electronic SPSS file (version 27, IBM). Regular reviews of the correct data transfer are conducted by assessors at the study site. The electronic data will be stored in a protected folder on a server at University Hospital Augsburg. Paper-based data are stored in a locked office at the study site.

**Pseudonymisation**

Data are assessed and analysed in pseudonymised form. For this purpose, a randomly generated numerical
Ethics approval and dissemination

The study protocol, the patient information and the informed consent form have been approved by the ethics committee of the Ludwig-Maximilians-University, Munich, Germany (reference number: 20-1041).

We plan to publish the findings in peer-reviewed journals and share our findings at academic conferences.

Trial registration and trial status

A WHO Universal Trial Number (U1111-1259-1956) has been obtained. The trial has been prospectively registered at the German Clinical Trials Register (DRKS00024802). The trial is currently open for recruitment. After 6 months, a total of 48 patients have been randomised at the date of submission of this paper.

DISCUSSION

Over the past years, the best technique for closure of the abdominal fascia has been extensively discussed. Nevertheless, complications like wound infections, burst abdomen and incisional hernias are still common. There is sufficient evidence for closure of the fascia in the context of elective surgeries by prospective trials and meta-analyses, leading to strong recommendations how to close the fascia in this setting. The last guideline of the European hernia society from 2015 recommends for elective midline incisions, to perform a continuous suturing technique using a slowly absorbable monofilament suture in a single layer aponeurotic closure technique. The closure should be done in a small bites technique with a suture to wound length ratio at least 4/1. Against this, there is only few and heterogeneous data concerning closure of midline incision after emergency laparotomy. There are new prospective trials on continuous versus interrupted abdominal wall closure in the context of emergency surgery, but results are still missing. It is widely known that emergency surgery is a risk factor for wound infections and fascia dehiscence leading to prolonged hospitalisation and a threefold higher risk of reoperations.

Some studies tried to cope with this risk factors for healing of the abdominal fascia by using additional retention sutures. These sutures are performed by stitches through the skin, subcutaneous tissue, rectus muscle and abdominal fascia and try to reduce tension on the running fascia suture. Although reduced rates of fascia dehiscence after the use of retention sutures could be shown, these full-thickness sutures never became popular in daily routine because of negative side effects like skin maceration and especially wound pain.

In order to find the best closure-technique for emergency midline laparotomies, further prospective trials are urgently needed. This RCT compares the most common closure technique of the abdominal fascia, the continuous sutting technique using a slowly absorbable monofilament suture in a small bites technique (two MonoMax loops), with the same technique in combination with single stitch retentions sutures (Vicryl 2 suture). To avoid the described complications—especially wound pain—these sutures do not include the whole abdominal wall but rather confine only on the fascial layer. These stitches are also made in wider distance to the fascia edge to prevent interference with the continuous fascial suture. As the combined primary endpoint, the incidence of burst abdomen by 30 days or incisional hernia within 12 months after surgery was chosen to assess the influence of both suturing techniques on the fascia healing in the emergency setting. Theoretically, a running suture and additional retention sutures combine the advantages of both suturing techniques. It is well known that one of the main risk factors for incisional hernias is postoperative surgical site infection. The interrupted sutures could prevent a dehiscence of the fascial layer although if the continuous suture loosens up due to local tissue infection or poor fascia conditions in the emergency setting. For this purpose, a rapidly absorbable suture can secure this early phase after surgery, which is crucial for incisional hernias. The only disadvantage of additional interrupted
sutures is that the insertion of additional suture material could cause pain or suture granulomas. Therefore, we use rapid absorbable sutures to minimise this risk in the long term. It must be mentioned that fascial closure with rapid absorbable sutures alone is not recommended anymore because of high rates of incisional hernias.23 Thus, rapid absorbable Vicryl sutures are only used as a supplement to the main closure technique in this trial with the advantages in respect to wound pain and granulomas shown above.

The pooled primary endpoint has the advantage of evaluating the effect of different suture techniques on both the rate of burst abdomen and incisional hernias. Furthermore, it is associated with a realistic case number for study implementation. A disadvantage of this could be an under-reporting of a difference in the incidence of burst abdomen, which is rather low compared with the rate of incisional hernias.

In summary, the CONIAC trial will assess efficacy and safety of two different abdominal wall closure techniques in patients undergoing emergency midline laparotomy. The results of this trial will help to improve short-term and long-term surgical outcomes and will hopefully provide further evidence to find the optimal closure technique of the abdominal fascia in the emergency setting.

CONTRIBUTORS SW, LATd, DV and MA designed the study protocol. MCS, DV and SW developed the evaluation plan. SW drafted the initial manuscript. MCS, DV, FS and MA critically revised the manuscript for important intellectual content. Final approval of the version to be published was given by all authors. DV, SW and MA took responsibility for the work and controlled the decision to publish. The corresponding author attests that all listed authors meet the authorship criteria and that no others meeting the criteria have been omitted.

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REFERENCES


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Patient information and consent form

„Value of abdominal wall closure with continuous suture in combination with retention sutures of the abdominal wall fascia after median emergency laparotomy. CONIAC-Studie („continuous and interrupted abdominal-wall closure”).”

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Dear Patient,
You will be asked whether you are willing to participate in a scientific study. In the following, we will present the main points that will help you to form an opinion. We thank you in advance for your cooperation and for taking the time to read this information.

The purpose of this study is to investigate two different suture techniques for closure of the abdominal wall and their effect on primary healing and development of abdominal wall hernias, so-called incisional hernias.

What is the purpose of this study?
In patients who require emergency surgery, a large, elongated abdominal incision is usually made to access the abdominal cavity. This abdominal incision can often cause problems despite a successful operation. For example, the most common complications are healing problems of the wound and the abdominal wall fascia. The abdominal wall fascia is a connective tissue structure that connects the muscles of the abdominal wall. This is opened during a longitudinal abdominal incision.

Wound infections, primary healing disorders of the abdominal wall fascia (so-called burst abdomen) or abdominal wall hernias may occur, which usually require a repeat operation. The frequency of these postoperative problems is largely related to the suture technique used to close the abdominal wall fascia. For this reason, many studies have been conducted over the past years to find the best method for closing the abdominal wall fascia.

There is evidence that continuous suturing with a slowly absorbable monofilament suture leads to fewer complications and abdominal wall hernias in planned elective surgery than closure of the fascia with interrupted sutures. For the closure of the abdominal wall during emergency surgery, which is primarily associated with an increased risk of a gaping wound, burst abdomen and consequently incisional hernia, no recommendation for a special suture technique can be given due to a lack of evidence.

The frequency of these abdominal wall complications also correlates with a number of other risk factors, such as anemia, malnutrition, chronic pulmonary disease, or even...
postoperative vomiting and bowel obstruction. In these cases, some studies recommend the use of additional retention sutures to reduce tension on the fascial suture and thus allow better healing. This may reduce the rate of abdominal wall hernias. However, there is a lack of reliable empirical data to make a clear recommendation for this technique.

Therefore, the aim of this study is to compare the established continuous suture of the abdominal wall fascia with a combination of continuous suture and interrupted retention sutures in terms of postoperative complications such as wound healing disorders, pain and abdominal wall hernias.

Here you can see again an overview of the advantages and disadvantages of the two techniques:

Control group - continuous suture:
- established suture technique
- less foreign material
- maximum approx. 23% probability of developing a healing disorder of the abdominal wall fascia

Intervention group - continuous suture with retention sutures:
- Combination of two established suture techniques
- additional reinforcement of the cranck wall fascia
- more foreign material and possibly more wound pain as well as granulomas
- possibly less frequent scar hernias and burst bellies (estimated approx. 13%)

How is this study conducted?
After inclusion in the study, random assignment to one of the two suture technique groups will be performed by a lottery procedure (randomization):
In the first group (control group), closure of the abdominal wall fascia is performed using continuous sutures, while in the second group (intervention group), closure is performed using continuous sutures in combination with interrupted retention sutures using the single button technique. You will not know which group you have been
assigned to. After the operation, it will be documented whether there were any complications of the abdominal wound. After discharge, you will also be called for clinical follow-up after 1 month and 1 year, and you will receive a questionnaire on quality of life and patient satisfaction. In the visit after 1 year, an ultrasound of the abdominal wall will be performed in addition to the physical examination.

**What risks or side effects may occur?**
You will not incur any additional risks or other disadvantages as a result of your participation in the study. Both suture procedures are established methods for closing the abdominal wall. Only an additional ultrasound examination of the abdominal wall will be performed 1 year after surgery. However, this examination method does not involve any risks as well as radiation exposure. No additional surgical steps are performed. No additional tissue will be removed and no additional medications will be administered. As part of the study, you will be asked to complete a questionnaire about your well-being before your surgery and at two specified times after surgery, and to present to our university outpatient clinic for clinical follow-up (1 and 12 months after surgery). There are no direct benefits to you, but you will contribute to the possible improvement of an established surgical method and a possible reduction in complications.

**Are there any costs or expenses for participating in the study?**
No. The examinations, treatments and medical procedures routinely performed on you during the operation and your stay after the operation are part of the normal treatment. Therefore, the cost of these procedures will be covered by your health insurance. There will be two study visits (at 30 days and 12 months postoperatively) at specified times after surgery. The presentation takes place via our university outpatient clinic, costs for this are borne by your health insurance and the University Hospital Augsburg.

**Is participation voluntary?**
Participation in this study is voluntary. You can refuse to participate without giving any reason. You may revoke any consent given at any time without giving reasons. You will not suffer any disadvantage for further treatment as a result of non-participation or discontinuation of participation. In case of withdrawal of your consent, no further data will be collected from you for the study.
Who reviewed this study?
The study protocol, patient information and informed consent were reviewed by the Ethics Committee of Ludwig-Maximilians-University Munich and by the central study secretariat at Augsburg University Hospital. It was checked whether your safety and your rights are protected when participating in the study. The ethical harmlessness was confirmed by the ethics committee of the Ludwig-Maximilians-University Munich.

To whom can further questions be addressed?
If you have further questions about this study, you can contact one of the study physicians, Director Prof. Dr. Matthias Anthuber, Dr. Sebastian Wolf, Mr. Dmytro Vlasenko or our study assistant Luis Arbona de Gracia (Tel.: 0821-400-2653; E-Mail: avt.studien@klinikum-augsburg.de).
Information on data protection

All scientific data obtained in the course of this study will be treated confidentially. The regulations on medical confidentiality and data protection will be observed. During the study, medical findings and personal information will be written down in your study file and stored electronically. The data relevant to the study will be stored in pseudonymized\(^1\) form, evaluated and, if necessary, passed on to authorized employees of Augsburg University Hospital in pseudonymized form for statistical evaluation.

Before being passed on to authorized employees of Augsburg University Hospital for statistical evaluation, certain information collected in the course of the study will be deleted from the pseudonymized data set. In particular, no name, date of birth or address will be passed on.

The evaluation will be returned to the Clinic for General, Visceral and Transplant Surgery. There will be no disclosure of patient data or pseudonymized data to other institutions or companies.

Decryption of pseudonymization\(^1\) will only occur in cases where your own safety requires it ("medical reasons"), if there are changes in the scientific question ("scientific reasons"), or upon withdrawal from the study for the purpose of data destruction. Decryption is only possible by authorized employees of Augsburg University Hospital.

As soon as it is possible according to the research or statistical purpose, the personal data will be anonymized\(^2\).

\(^1\) "Pseudonymization" means the processing of personal data in such a way that the personal data can no longer be attributed to a specific data subject without the use of additional information ("key"). This additional information is kept separately and is subject to technical and organizational measures that ensure that the personal data cannot be assigned to an identified or identifiable natural person.

\(^2\) "Anonymization" is the alteration of personal data in such a way that the data subject can no longer be identified, or can be identified only with a disproportionate expenditure of time and money.

In addition to the researchers and statisticians involved in the study, access to your pseudonymized data may be granted to investigators, the institutional review board, or the relevant government authorities, as appropriate.

As a study participant, you may be contacted by us by telephone, mail, and email for study purposes as part of the study.

The study management will take all reasonable steps to ensure the protection of your
data in accordance with European Union data protection standards. The data will be secured against unauthorized access. The data will be stored at Augsburg University Hospital for a maximum of 10 years. The data will be used exclusively for the purposes of this study. With your consent, your pseudonymized data may also be used for future research projects on the abdominal wall closure method.

You have the right to request information about the stored personal data from the person responsible (see below). Likewise, you may request the correction of inaccurate data as well as the deletion of the data.

Who is responsible for data processing and whom can I contact?
Department for General, Visceral and Transplant Surgery
University Hospital Augsburg
Stenglinstr. 2
86150 Augsburg
Phone: 0821-400-2653
E-mail: avt.studien@uk-augsburg.de

If you have any concerns about data processing and compliance with data protection requirements, you can contact the facility's data protection officer. You can reach our data protection officer at:
Augsburg University Hospital
Data Protection Officer
Stenglinstr. 2
86150 Augsburg
Phone: 0821-400-4113
E-mail: datenschutz@uk-augsburg.de

In the event of unlawful data processing, you have the right to complain to the following supervisory authority:

Bavarian State Commissioner for Data Protection (BayLfD)
Prof. Dr. Thomas Petri
Postal address: Postfach 22 12 19, 80502
Home address: Wagmüllerstr. 1, 80538 Munich, Germany
Tel: 089-212672-0
Fax: 089-212672-50
Declaration of consent

I have read the written patient information and was also informed verbally by Mr./Mrs. __________________ about the aim and procedure of the study as well as about possible advantages and disadvantages in a detailed and comprehensible manner. I had the opportunity to ask questions during the information session. All my questions were answered to my satisfaction. I voluntarily agreed to participate in the study. I had sufficient time to make my decision. I have received a copy of the information leaflet and the consent form.

Data protection

I am aware that personal data will be processed during this study. The data will be processed in accordance with legal provisions and requires the following declaration of consent in accordance with Art. 6 (1) a of the General Data Protection Regulation:

I have been informed and voluntarily consent that my data collected in the study, in particular information about my health¹, may be recorded in pseudonymized form for the purposes described in the information notice, evaluated and, if necessary, also passed on in pseudonymized form to authorized employees of Augsburg University Hospital and the University of Augsburg. In addition to the scientists and statisticians involved in the study, access to your pseudonymized data may be granted to investigators, representatives of the ethics committee, the institutional review board, or the relevant government authorities, as appropriate.

Third parties will not be given access to personal records. Any publication of study results will be in anonymized form.

¹ According to Art. 9 (1) of the DSGVO, health data are special category personal data, the processing of which requires the explicit consent of the study participant. The same applies to data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, as well as to the processing of genetic data, biometric data uniquely identifying a natural person, data concerning sex life or sexual orientation.

The personal data will be anonymized as soon as this is possible according to the research purpose. The data will be stored for a maximum of 10 years after completion of the study. I am aware that this consent can be revoked at any time in writing or verbally without giving reasons and without any disadvantages for me. The legality of the data processing carried out until the revocation is not affected by this.
I consent to being contacted by mail, by e-mail and by telephone in the context of the study.

**Please mark with a cross where applicable:**

- O I agree to participate in the study and use my pseudonymized data for the current research project.
- O I consent to the use of my anonymized data for future research projects at Augsburg University Hospital on the abdominal wall closure method.

______________________________

name, patient

______________________________

date, signature patient

I have explained all relevant details about this study and data protection to the person indicated above. The patient has been given a copy of the patient information about the study and the information about data protection.

______________________________

name, physician

______________________________

date, signature physician