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 creek 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\(^2\).

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\(^1\) "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: Wagnmüllerstr. 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:**

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

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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.

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name, physician

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date, signature physician