Evangelisches Klinikum
Köln Weyertal

Patient sticker

Academic teaching hospital of the University of Cologne

Clinic for General and Visceral Surgery

Chief physician:
Priv.-Doz. Dr. med. Claudia Rudroff
Phone: 0221 479-5100
Fax: 0221 479-5104
E-mail: viszeralchirurgie@evk-koeln.de

Patient information and declaration of consent for the research project:

Interventional pilot study comparing a biological mesh with a standardized synthetic mesh in interdisciplinary laparoscopic resection rectopexy (RRP) in combination with a mesh sacrocolpopexy (SCP) (short: BioSynIRS)

Patient information

Dear patient,
We would like to ask you whether you would like to take part in a scientific study. In this patient information leaflet you will find everything you need to know about the study.

Please read this information carefully. Your doctor will talk to you about the study and answer your questions.

We have 28 people taking part in the study.

This study is planned and carried out by Evangelisches Klinikum Köln Weyertal gGmbH (EKK Weyertal).

Our institution finances the study itself.
The study was submitted to the responsible ethics committee. It raised no objections.

Your participation in this study is voluntary. You can also end your participation at any time during the course of the study. You do not have to justify this. This will not have any disadvantages for your medical treatment or your relationship with your treating physician.

If you have any further questions about the study now or later, please feel free to contact us.
Please contact
PD Dr. Claudia Rudroff
Tel: 0221/479-5100
E-Mail: Claudia.Rudroff@evk-koeln.de.

Why is this study being conducted?

With your condition, the emptying of the bowel is severely impeded. This is because the bowel is elongated and sagging. To improve the emptying of the bowel, part of the bowel should be shortened and reattached in a stretched form.

You also suffer from the fact that your rectum has descended. To correct this, the uterus or vagina should be attached to the sacrum. This is usually done with the help of a fine plastic mesh.

During bowel surgery, pathogens can be released that infect the mesh. In addition, the plastic mesh can grow together with the surrounding tissue in such a way that it can damage it. In order to reduce these risks, we are investigating in this study whether this is possible through the use of biological meshes.

For this purpose, the results of two groups of patients are compared with each other. In one group, a standardized, synthetic mesh is used. The other group of participants receives a biological mesh.

How does the study work?

The study is expected to last 12 months for each participant.

As a participant in this study, part of your bowel will be surgically removed and this shortened, stretched section of bowel will be reattached with a suture. The pelvic floor is then surgically lifted. This is done by attaching it with the help of a biological mesh around the cervix or to the front and back of the vaginal stump and fixing it to the sacrum on one or both sides with a suture. This combined procedure is performed in a single operation.

The surgeons are experts from various specialist fields. The bowel surgery is performed by a surgeon, Dr. Claudia Rudroff, MD. The correction of the pelvic floor prolapse is performed by a gynecologist, Dr. Sebastian Ludwig. Both surgeons are specialists in their respective fields. Such a combined procedure is referred to as "interdisciplinary surgery". The procedure as such is the same for both groups (see above). The only difference is the type of mesh - synthetic or biological, which is used for pelvic floor correction.

The surgical procedure is performed laparascopically. This means that you will be operated on very gently. The instruments required for the procedure are inserted into the abdominal cavity through small skin incisions of between 5 and 25 mm. This means that you will experience less pain after the operation and the scars will heal more quickly.

The details of the operation, its risks and possible complications as well as alternative treatment options are explained in detail, separately, verbally and in writing before the operation.

Your inpatient stay usually lasts between 7 and 14 days. You will then be re-examined at regular intervals. You will be examined for the first time after 4 weeks to assess the progress shortly after the operation. You will be examined again after 6 and 12 months to document the long-term success. These follow-up examinations are also the medical standard at the clinic outside of this study.

The study participants are randomly assigned to one of two equally sized treatment groups (like tossing a coin). This is called randomization. One group is operated on with a plastic mesh, the other group with a biological mesh.

As part of the study, the results of the two test groups are compared with each other. Your doctor knows which treatment you will receive. After all, you will be operated on by him/her. However, you do not know which mesh will be used in the

operation is used. This is called blinding. The doctors who carry out the follow-up examination also do not know which of the two meshes they were operated on with. Blinding is necessary in order to obtain examination results that are as unbiased as possible.

Are there any personal benefits from participating in the study?

You personally will not benefit directly from your participation. However, the results of the study may help other people in the future.
At the end of the study, all participants will be informed about the type of mesh used in their case.

What are the risks associated with participating in the study?

Synthetic meshes have been used for decades in pelvic floor surgery and are considered a standard procedure. The mesh remains permanently in the patient's body. In some cases, its proximity to the other pelvic organs can lead to infection of the mesh over time with inflammation in its surroundings, adhesions with surrounding structures and ingrowth into neighboring organs. These conditions can lead to serious complications for individual patients, which may necessitate a repeat operation. Allergies to the mesh material can also occur. However, this is not yet known for the material used in this study.

The use of a biological net appears to be a sensible alternative. The biological material dissolves after 12 to 18 months and has a low risk of mesh infection. There is no risk of permanent ingrowth into the surrounding tissue and organs. However, the tissue may lose the desired stability after the mesh has dissolved. In some cases, this could lead to a recurrence of pelvic floor prolapse. However, it is still unclear whether a biological mesh stabilizes the pelvic floor in the same way as a synthetic mesh in the long term.

To date, well over 1,000 patients worldwide and more than 50 patients with various diseases have been treated with a biological mesh at our clinic.
For some time now, biological meshes have also been routinely used for fixing the bowel in isolated bowel prolapse. The results to date have been

The results are promising and no mesh-related allergies or complications have been observed. However, long-term results on this topic are lacking.

In this study, either the standard synthetic mesh or a biological mesh will be used in your operation. This is the type of mesh described above, which has already been used successfully for so-called mesh rectopexy.
This mesh is made from the processed intestinal wall of pigs.

Who is not allowed to take part in the study?

Pregnant women and nursing mothers are not allowed to take part in the study. Pregnancy must also not be planned during this period. Women of childbearing age must use reliable contraception during the study. The doctor will inform you about this. A pregnancy test will be carried out before the start of the study. Should you nevertheless become pregnant during your participation in the study or if there is a reasonable suspicion of pregnancy, please inform us immediately.

Patients with an allergy to animal protein are excluded from participation.

What other options are there outside the study?

You have the option of not having an operation. You can use other measures to regulate your bowel movements and stabilize the pelvic floor.

You can have your complaints treated in two or three individual operations. These are then carried out separately by different specialist departments.

You also have the option of making a binding decision during the operation to use a plastic mesh or a biological mesh. In this case, however, random allocation to one of the treatment groups is no longer possible. This would exclude you from the study.

Are there any additional costs?

Neither you nor your health insurance company will incur any additional costs by participating in the study.

Was insurance taken out for this study?

We would like to point out that no special insurance has been taken out for the study, as the surgical procedure and the follow-up examinations after discharge from hospital correspond to the current medical standard in our clinic. This means that all patients who are not participating in this or any other study on this topic will be treated in the same way. This means that no additional insurance, known as trial insurance, is necessary.

What do we expect from the study participants?

We ask you to attend all scheduled follow-up appointments. This is your personal contribution to the success of the study.

Information on data protection

Evangelisches Klinikum Köln Weyertal (EKK Weyertal) is responsible for data processing in this study. The legal basis for the processing is personal consent (Art. 6 para. 1 lit. a, Art. 9 para. 2 lit. a GDPR). The data will be treated confidentially at all times.

The data is collected exclusively for the purpose of this study described above and is only used within this framework.

The data collected also includes personal identifying data such as age at surgery and sensitive personal health data.
All data by which you could be directly identified, e.g. your name or date of birth, is replaced by an identification code (pseudonymized). This makes it almost impossible for unauthorized persons to identify you. Identification is only possible via the pseudonymization list. This is only accessible to the scientists involved. Nevertheless, there are confidentiality risks with every collection, storage, use and transmission of personal data, e.g. it may be possible to identify the person concerned in individual cases.

The data is stored Evangelisches Klinikum Köln Weyertal (EKK Weyertal). We only store the personal data for as long as is necessary for the above-mentioned purpose. The data will be deleted after 10 years at the latest.

We do not transfer personal data to other institutions in Germany, the EU, to a third country outside the EU or to an international organization.

The data can be used for scientific publications. The data is used in a form that does not allow any conclusions to be drawn about the individual study participants (anonymized).

Consent to the processing of your data is voluntary. You can revoke your consent at any time without giving reasons and without any disadvantages for you. Data will then no longer be collected. This does not affect the lawfulness of the processing carried out on the basis of the consent until revocation.

In the event of revocation, you can request the deletion of the data collected. The data can also be used in anonymized form if you consent to this at the time of your revocation.

You have the right to receive information about the data, also in the form of a copy free of charge. In addition, you may request the rectification, blocking, restriction of processing or erasure and, if necessary, the transfer of data.

In these cases, please contact us if you have any further questions about data protection and the handling of data or in the event of revocation:

PD Dr. Claudia Rudroff
Chief Physician of the Department of Visceral Surgery, Functional Surgery of the Lower Gastrointestinal Tract (UGI)
Clinic for General and Visceral Surgery Evangelisches
Klinikum Köln Weyertal (EKK Weyertal) Weyertal 76
50931 Cologne
Phone: +49-221-479-5100
Fax: +49-221-479-5104
E-Mail: claudia.rudroff@evk-koeln.de

If you have any questions about data processing and compliance with data protection, please contact the data protection officer:

Headmistress Stephanie Zurmöhle

Data Protection Officer of EKK Weyertal Evangelisches
Klinikum Köln Weyertal (EKK Weyertal) Weyertal 76
50931 Cologne
Phone: +49-221-479-1040
E-mail: stepahanie-zurmoehle@evk-koeln.de

You also have the right to lodge a complaint with any data protection supervisory authority. You can find a list of the supervisory authorities in Germany at:
https:/ / w w w . b f d i . b u n d . d e / D E / I n f o t h e k / A n s c h r i f t e n _ L i n k s / a n s c h r i f t e n _ l i n k s - n o d e . h t m l
The supervisory authority responsible for you:
State Commissioner for Data Protection and Freedom of Information North Rhine-Westphalia P.O. Box 20 04 44
40102 Düsseldorf
Switchboard: +49 (0)211 / 38424 - 0
poststelle@ldi.nrw.de

Patient information and declaration of consent for the research project:

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Declaration of consent

I was informed by _____ about the study. I have received and read the written information and declaration of consent for the above-mentioned study. I was informed in detail in writing and verbally about the purpose and course of the study, the opportunities and risks of participation and the associated rights and obligations. I had the opportunity to ask questions. These were answered satisfactorily and completely. In addition to the written information, the following points were discussed:

_____

_____

My consent to participate in the study is voluntary. I have the right to withdraw my consent at any time without giving reasons and without incurring any disadvantages.
I know that neither participant insurance nor commuting accident insurance has been taken out for this study.

The processing and use of personal data for the above-mentioned study is carried out exclusively as described in the information on the study.

I hereby consent to the processing of my personal data as described, in particular health data.

I hereby give my consent to participate in the above-mentioned study.

_____

Name of the participating person in block capitals

_____

Place, Date and signature of the participating person

_____

Name of the doctor obtaining the declaration of consent in block capitals

_____

Place, Date and signature of the person providing information