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Vaginal reconstruction using a personalized degradable layered graft made from the patient's own tissue

Submission date
22/03/2026

Recruitment status
Recruiting

Registration date
24/03/2026

Overall study status
Ongoing

Last Edited
23/03/2026

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to find out whether a new type of graft made from a patient's own vaginal tissue can be used safely and effectively during vaginal reconstruction surgery. The graft is made in the operating theatre from a small sample of the patient's tissue and placed into the surgical area to help healthy tissue grow during healing.

Who can participate?
Women aged 15 years and older who need surgery for vaginal stenosis, vaginal atresia or a horizontal vaginal septum may be able to take part. Women who have had similar surgery in the past using tissue taken from another part of the body may also be invited to join the control group. People cannot take part if they are receiving chemotherapy or certain immune treatments, have a known allergy to bovine products, have had radiation to the pelvis, or have specific immune conditions that affect the vagina.

What does the study involve?
Participants who need surgery will receive the new graft during their operation. A small tissue sample will be taken, prepared on a biodegradable mesh, and placed into the surgical area. After surgery, participants will be monitored for any problems and will attend check ups at about 6 months, 1 year and 2 years. These visits will include examinations, tissue samples from the graft area, and questionnaires about symptoms, sexual health and quality of life.

Participants in the control group will not receive surgery as part of this study. They will complete a set of questionnaires once. Their results will be compared with the results of the group receiving the new graft.

What are the possible benefits and risks of participating?
There may be no direct benefit. However, the new graft may help healthy vaginal tissue grow after surgery, which could improve healing and reduce complications. Risks include the usual risks linked to surgery, such as infection, bleeding or pain, as well as a small chance of allergic reactions. Participants will be monitored closely to manage any problems that arise.

Where is the study run from?
The study is run from Copenhagen University Hospital, Rigshospitalet, in Denmark.

When is the study starting and how long is it expected to run for?
The first participants are expected to join the study from 01 April 2026. The study is expected to continue until 2033.

Who is funding the study?
The study is funded by the Independent Research Fund Denmark and two grants from the Novo Nordisk Foundation.

Who is the main contact?
Professor Magdalena Fossum, mfos0019@regionh.dk

Contact information

Type(s)
Principal investigator, Scientific, Public

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Public, Scientific

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Additional identifiers

Study information

Scientific Title
Using the Personalized Layered Autologous Tissue Expansion graft in VAGinal reconstructive surgery and patient reported outcomes measures for comparison with previously treated patients

Acronym
PLATE-VAG

Study objectives
The aim of the study is to evaluate the feasibility, safety, and clinical use of a new perioperative method for autologous tissue expansion in vaginal reconstructive surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/10/2025, De Videnskabsetiske Komiteer for Region Hovedstaden - The Research Ethics Committee for the Capital Region (Borgervænget 3, ST, Copenhagen, 2100, Denmark; +45 3866 6395; vek@regionh.dk), ref: H-25043127

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Historical

Assignment
Single

Purpose
Device feasibility, Treatment

Study type(s)

Health condition(s) or problem(s) studied

Vaginal atresia, vaginal stenosis and vaginal septum needing surgical intervention.

Interventions
The participants in the study will consist of two groups
1. Patients diagnosed with a vaginal stenosis, vaginal atresia or vaginal horizontal septum with an indication for surgical correction (intervention group)
Intervention: Surgical intervention will be performed withan autologous surgical graft called the Perioperative Layered Autologous Tissue Expansion (PLATE) graft. Briefly, the PLATE-graft consists of a minced biopsy of the patient's own vaginal mucosa, spread on a biodegradable mesh and imbedded in a collagen hydrogel. The collagen hydrogel is compressed to expel its water content, and then sutured into the surgical vaginal wound to allow for tissue expansion during postoperative healing. The PLATE-graft is constructed perioperatively inside the operating theatre, next to the patient within 30 minutes.

2. Control patients who have previously undergone surgical correction for vaginal stenosis, vaginal atresia or vaginal horizontal septum using autologous donor tissue from another organ (e.g. buccal mucosa, intestine or skin) (control group).

The intervention group and the control group will both answer questionnaires related to female health after at least 1 year after vaginal reconstructive surgery

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Vaginal patency measured using vaginal patency, stricture evaluation, biopsies from the graft area at 6 months, 1 year and 2 years postop.

2. Adverse events measured using clinical evaluation, pain medication at 2 weeks, 6 months, 1 year, 2 years after surgery

Key secondary outcome(s)
1. Patient QoL and symptom scores before and after the surgery measured using validated questionnaires; FSFI, FSD and WHO QOL brief to the intervention group and the historic control at Intervention group: Preop, 6 months, 1 year and 2 years after surgery. Control group: 1 time point at any time period after surgery

Completion date
01/01/2033

Eligibility

Key inclusion criteria
Control group:
1. Can receive information in Danish or English and provide a signed informed consent
2. Previous surgical reconstruction of the vagina using implantation of non-vaginal tissue grafts or flaps due to stenosis, iatrogenic damage or congenital malformation

Surgical group:
1. Can receive information in Danish or English and provide a signed informed consent
2. Indication for surgical reconstruction of vagina due to stenosis, iatrogenic damage or

congenital malformation that would require implantation of non-vaginal tissue grafts or flaps to restore an epithelial lining

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
15 Years

Upper age limit
100 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
For both control and surgical groups:
1. Active chemotherapy or other immunomodulating treatment
2. Known allergy towards bovine proteins/products
3. Previous radiation therapy to the pelvic area or lower abdomen
4. Diagnosis of known immunological condition related to the vagina (e.g. lichen planus)

Date of first enrolment
01/04/2026

Date of final enrolment
01/01/2031

Locations

Countries of recruitment
Denmark

Study participating centre
Copenhagen University Hospital, Rigshospitalet
Dept. of Pediatric Surgery
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Sponsor information

Organisation
Copenhagen University Hospital

ROR
https://ror.org/05bpbnx46

Funder(s)

Funder type

Funder Name
Danmarks Frie Forskningsfond (DFF1, Independent Research Fund Denmark)

Funder Name
Novo Nordisk Foundation Professorship in Pediatric Surgery grant

Funder Name
Novo Nordisk Found Pioneer grant

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available