Pedicled Peritoneum Vaginoplasty in feminizing genital Surgery; implementation according to IDEAL framework

Published: 02-11-2022
Last updated: 27-12-2024

Primary Objective: To assess the safety of the single flap peritoneum vaginoplasty procedure by studying adverse events and complications during, directly after and within 90 days of the operation. Secondary Objectives: - To assess short- (12 weeks...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51660

Source
ToetsingOnline

Brief title
PeriVaS

Condition

- Other condition
- Reproductive tract and breast disorders congenital
- Vulvovaginal disorders (excl infections and inflammations)

Synonym
genderdysforia with wish for gender affirming surgery and acquired or congenital diminshed vaginal depth

Health condition

genderdysforie

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: genital surgery, IDEAL, peritoneum, vaginoplasty

Outcome measures

Primary outcome

The primary endpoint is the complications up until 90 days postoperative.

Complications are reported by full description of the event and eventual

treatment. They are classified according to the Clavien-Dindo classification.

Secondary outcome

Technical outcomes:

Changes made to any of the steps in the procedure,

reasons for change of procedure, successful technical completion, operative

time

and subjective experience of surgeons.

Intra- and direct post-operative outcomes:

Dimensions (depth and width) of neovagina, measured with

measuring dilatators, blood loss, adverse events, conversion of procedure

for successful result of procedure (e.g., to open),

length of hospital stay.

Clinical outcomes: During follow-up at 3/6/12 months:

Dimensions (depth and width) of neovagina

micturition: infections, characteristics of voiding jet

Pain: score, characteristics, location and treatment

Sexual function: sensitivity of clitoris (normal, hyper- or

hyposensitive), ability to engage in penetrative sex, ability to orgasm.

Satisfaction with aesthetics of vulva and vagina.

Study description

Background summary

Vaginoplasty is the surgical (re)construction of a neo- vagina. At the moment, the standard procedure to construct a neo-vagina is a penile inversion vaginoplasty. Where the skin of the penis is used as lining of the neovagina. When there is insufficient or no penile skin available, up to now the standard procedure is to form a neovagina through a diversion of the large bowel. This enatials extensive colorectal surgery with potential major morbidity. Another complication of this procedure that is more frequent, is malodorous excessive discharge due to colitis of the bowel conduit. Furthermore, ant theoretical risk of malignancy of the diversion vagina is present due to the chronic inflammations . A less morbid peritoneum *pull down* vaginoplasty is a well-known and widely used alternative technique for cis-women who are born without a vagina. However, the technique limits the maximum achievable depth and subsequent functional outcome. By using a single pedicled peritoneum flap, it is possible to create more depth.
In recent years, the peritoneum vaginoplasty is also performed in transgender women, with reported good results [4-6]. However, in these publications the peritoneum is either used as small flaps to deepen the vagina, or the peritoneum is pulled down. We propose to introduce an optimized technique, based upon a single pedicled peritoneal flap, which is brought down and sutured in the vaginal cavity to form a cylinder. The perioperative risks are suspected to be substantially lower with minimal chance of bowel leakage and thereby the risk on re-interventions or a temporary stoma. Second, at long term the chance of malodorous discharge and chronic inflammation is lower, which is expected to result in improved satisfaction and sexual function.
This study aims to assess if the single flap pedicled peritoneum vaginoplasty is safe and feasible. There are two groups who are eligible to undergo this

procedure: 1) trans-women who have not enough penile skin to undergo the standard vaginoplasty procedure or who have an obliteration of the primary neovagina; 2) cis-women who do not have a vagina due to a congenital condition or a previous malignancy.

Study objective

Primary Objective:
To assess the safety of the single flap peritoneum vaginoplasty procedure by studying adverse events and complications during, directly after and within 90 days of the operation.

Secondary Objectives:
- To assess short- (12 weeks after operation) and long-term (between 3-12 months) physiological and clinical outcomes to assess the success of the technique in terms of functionality.
- To assess the technical success and development of the procedure, and to work towards a standardized optimized version.

Study design

This study is a prospective intervention study.

The study design is according to the IDEAL framework for surgical innovation that is innovative, but for which already some evidence exists regarding safety and feasibility. See table 1 in chapter 1 for a detailed overview of stages. Stage 1 of IDEAL entails a proof of concept in 3 patients, the aim is to see if the intervention is feasible and safe. Stage 2a involves a prospective case series of 10 patients. Both stages are single center and surgeons will be the same, as the aim is to develop the technique until it is stable. Safety is the most important outcomes in both stages

The duration of the study will be two years, or less if the sample size is met before. The results of this study will be compared with results from literature of the sigmoid vaginoplasty, to determine if we will proceed to the next IDEAL stages (pre-RCT study and RCT). The number of patients that are excluded and the reason for exclusion will be registered.

Intervention

All subject in this study will undergo a laparoscopic pedicled single flap peritoneum vaginoplasty.

Study burden and risks

The burden of the procedure is comparable to the procedure of usual care (with

the use of sigmoid diversion). Our hypothesis is that there will be shorter recovery, because the bowel is not affected and no anastomosis will be made with associated morbidity. There is no extra burden of the study for the participants, apart from undergoing the intervention. The pre-operative and post-operative care are the same, as is the follow-up schedule. There are no extra physical examinations or other tests. No extra visits are needed. If the operation is not successful; does not provide a functional vagina, there is always the option to perform an bowel diversion vaginoplasty afterwards. For an extensive description of risks associated with vaginoplasty, see document B2.5 NFU risicoclassificatie.
The risks of the intervention are related to the approach and the anaesthesia. The chance of damage to nearby structures (rectum, urethra) because of the open approach phase where the cavity is created, is the same as in standard care (bowel vaginoplasty). The risk of damaging structures during laparoscopy is identical as during other laparoscopies. There is risk of damaging bowel, bladder, bleeding or infection. Furthermore there is risk of damaging structures during the start of laparoscopy, infections of the incisions for the trocars. In addition to operation risk, there is the risk of anesthesia related complications. Because no bowel anastomosis is created, the risk of bowel leakage or necrosis of the diverted bowel is non-excistent.

Contacts

Public
Amsterdam UMC

Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific
Amsterdam UMC

Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Indication for vaginoplasty:
o transgender women: indication for vaginoplasty according to the standards of care and not
eligible to undergo penile inversion vaginoplasty due to a shortage of penile/scrotal skin.
o Cis women: women with congenital vaginal agenesis or acquired diminished vaginal depth
- Age of 18 years or higher
- Able to give informed consent

Exclusion criteria

- Contra-indication for laparoscopic surgery
- Smoking (cessation for at least 6 weeks)
- BMI 18 < or >30 kg/m2
- Status after radiotherapy of the small pelvis

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-05-2023
Enrollment:	13
Type:	Actual

Ethics review

Approved WMO Date:	02-11-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL80365.029.22