A randomized clinical trial to study results of vaginoplasty with and without the use of additional full thickness skin graft in male to female transsexuals

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The aim of this study is to measure if there are differences in maintaining vaginal depth and in aesthetic results between patients who underwent construction of a neo-vagina with penile skin only, or with penile skin combined with FTG.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37824

Source
ToetsingOnline

Brief title
Vaginoplasty * a randomized clinical trial

Condition

- Other condition

Synonym
gender dysphory / gender identity disorder

Health condition

gender dysphorie

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: full thickness skin graft, gender reassignment surgery, plastic surgery, vaginoplasty

Outcome measures

Primary outcome

The primary end point of the study is vaginal depth and width. Measurements will be taken will be taken per-operatively, at six months and at one year after surgery. Depth and width of the vagina at six months and one year will be compared to measurements taken during the operation. Postoperatieve values will be compared to per-operative values in order to assess the amount of shrinkage.

Secondary outcome

Secondary outcomes are the aesthetic result, patient satisfaction, complications and reoperations. Aesthetic results will be assessed by patients, surgeons, and independent observers. These measurements will be performed at 6 months and one year after the last surgery. All complications and reoperations will be registered.

Study description

Background summary

Gender reassignment surgery is still shrouded in secrecy. There are only few centres where this surgery is performed in a limited number of countries. The

number of scientific publications in this area is very linited and no studies are performed to objectively assess this type of surgery.
Vaginoplasty is part of surgical reassignment of male to female transsexuals. The use of inversed penile skin has been wide spread in the construction of the neo-vagina of male to female transsexuals. The rationale behind this choice is that there is less shrinkage of the vascularised skin of the penis than of the full thickness skin graft (FTG) taken from elsewhere. In the case of a too small penis, the deepest part of the vaginal cavity is lined with a FTG, whilst the rest of the cavity is lined with penile skin. In recent years there has been a tendency to line most of the vaginal cavity with FTG*s and use the penile skin mostly for the shaping of the vulva. Stating that the use of more penile skin for the vulva gives a better esthetical appearance. However, there is no consensus about the optimal technique and outcomes of vaginoplasty have never been assessed in an objective manner.

Study objective

The aim of this study is to measure if there are differences in maintaining vaginal depth and in aesthetic results between patients who underwent construction of a neo-vagina with penile skin only, or with penile skin combined with FTG.

Study design

Randomized double blinded interventional study and a parallel observational cohort study.

Intervention

Patients whom meet the above mentioned criteria will be operated by a plastic surgeon of the gender team. Vaginoplasty will be performed in all patients. Patients eligible for the randomized trial will be randomized to treatment group 1 or 2 on the morning of the operation. In treatment group 1, only the penile skin will be used for construction of the vagina, in treatment group 2 penile skin + FTG will be used for the construction of the vagina. In the observational study group penile skin + FTG will be used for the construction of the vagina. Further treatment will be as written in the already existent protocols.

Study burden and risks

With regard to the intervention no extra burden will be placed on the patient. There are no extra risks involved in either operation as both methods of vaginal reconstruction are already being used regularly by the participating surgeons. Treatment and follow-up is exactly as in the existing protocol. The only extra burden on the patient comprises the time to fill in the

questionnaires. Admission time and the frequency of out patient visits will be the same as in the normal treatment (prior protocol).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

male to female transsexual older than 18 years
willing to undergo the sex reassignment surgery by means of a vaginoplasty
willing to participate
BMI < 30
able to fill in informed consent
able to fill in questionnaires

Exclusion criteria

BMI > 30
IQ under 90
Smoking
circumcision
For randomized group: penis length shorter than 12 cm

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-08-2012
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	01-06-2012
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	NL39075.029.11