Robot-assisted laparoscopic laparoscopic colpectomy in female-to-male transgenders

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feasability of a robot-assisted laparoscopic, single colpectomy in female-to-male transgenders who already had their uterus removed.

Ethical review	Approved WMO
Status	Completed
Health condition type	Vulvovaginal disorders (excl infections and inflammations)
Study type	Interventional

Summary

ID

NL-OMON54944

Source
ToetsingOnline

Brief title
ROCCY study

Condition

- Vulvovaginal disorders (excl infections and inflammations)

Synonym
vaginal removal, vaginectomy

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: colpectomy, laparoscopic surgery, pilot, transgender

Outcome measures

Primary outcome

Surgical complications during, right after or within 6 weeks after surgery and

long-term complications 3 months after surgery.

Secondary outcome

Voiding function, quality of life and experience after the surgery

Study description

Background summary

During sex change surgery from female-to-male a colpectomy (removal of the vagina) is performed to lower the risk of complications after phallo- or metadoioplastic (the surgical addition of a penis) with urethral lengthening. Until recently, the colpectomy was performed vaginally after the removal of the uterus. Recently, we have described a robot-assisted laparoscopic method to remove the uterus and vagina in one surgery. We have seen a drastic decrease in complications comparing the vaginal colpectomy with the robot-assisted laparoscopic colpectomy combined with hysterectomy (the extended colpectomy). But until now, transmen who had their uterus already removed had only one option: vaginal colpectomy. Yet, it is possible to perform a robot-assisted laparoscopic colpectomy after hysterectomy (the single colpectomy) and this is performed in New York already. With this pilot study we will determine 1) feasibility of the robot-assisted laparoscopic single colpectomy and 2) ethical accountability of a future randomised controlled trial comparing vaginal colpectomy with the single robot-assisted laparoscopic colpectomy.

Study objective

feasability of a robot-assisted laparoscopic, single colpectomy in female-to-male transgenders who already had their uterus removed.

Study design

a pilot cohort study comparing complication outcomes with a cohort of vaginal,

single colpectomy patients from a study.

Intervention

A robot-assisted laparoscopic, single colpectomy

Study burden and risks

The burden are laparoscopic incisions (vaginal surgery does not create any abdominal scars) and time investment in filling out questionnaires of an expected 20 minutes. Previous studies show that the robot-assisted laparoscopic, extended colpectomy has lower risks on surgical complications. Therefore, we hypothese that single colpectomy will also lower the risks for the participating patient.

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

- female-to-male transgender
- indication for colpectomy (urethral lengthening, vaginal dysphoria, complaints as vaginal discharge)
- previous hysterectomy

Exclusion criteria

- colpectomy because of other reasons then gender dysphoria
- contra-indication for laparoscopic surgery

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	19-06-2021
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	04-05-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	07-01-2022
Application type:	Amendment
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	NL75085.029.20