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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28152

Source
Nationaal Trial Register

Brief title
ROCCY study

Health condition

genderdysphoria

Sponsors and support

Primary sponsor: Amsterdam UMC, VUmc
Source(s) of monetary or material Support: not applicable

Intervention

Outcome measures

Primary outcome

Major and minor complications during, directly after, within 6 weeks or within 3 months after surgery.Complications that are expected as part of this outcome are:
Subcutaneous insufflation; urinary tract injury; intestinal injury; conversion to vaginal surgery; haemorrhage (bloodloss >1000ml); urinary tract infection; urinary retention; fistula; wound infection; fever eci

Secondary outcome

Surgical outcomes: blood loss, surgery time, console time

Post-surgery outcomes: hospital stay, need for prolonged catheterisation, and/or clean intermittend intermittent catheterization (the patient catheterizes himself) because of post voiding residue after surgery
IPSS* and uroflowmetry (pre and postoperative)

Patient outcomes: quality of life (SF36), satisfaction

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

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.

Study design

- Perioperatively; - 6 weeks & 3months postopertively

Intervention

Robot-assisted laparoscopic colpectomy

Contacts

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Eligibility criteria

Inclusion criteria

- age 18-80

- 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
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2021
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9303
Other	Amsterdam UMC : 2021.0062

Study results