RCT to determine Quality of Life after total laparoscopic hysterectomy when randomizing between discharge on day of surgery vs admittance.

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The primary objective of this study is to prove that a Total Laparoscopic Hysterectomy performed with sameday discharge is feasible and that it leads to equal levels of Quality of Life post-operative compared with one night admission.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Obstetric and gynaecological therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON53000

Source
ToetsingOnline

Brief title
Same day discHarge aftEr Laparoscopic hysTERectomy (SHELTER trial)

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
Total Laparoscopic Hysterectomy; uterus extirpation through laparoscopic surgery

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum

Source(s) of monetary or material Support: Maatschap Gynaecologie Máxima Medisch Centrum

Intervention

Keyword: Quality of Life, Same day discharge, Total Laparoscopic Hysterectomy

Outcome measures

Primary outcome

The primary outcome of this RCT is the recovery and satisfaction after surgery, measured with the Promis Physical Function - Short Form at 1, 3 and 7 days post-operative. The quality of life will be measured at these same time points by the EuroQol-5.

Secondary outcome

The secondary outcomes are the post-operative complications, operative characteristics, duration of surgery, operating room occupancy, time to discharge, time to first voiding, admission days, (re)admission, (re) evaluation, pain (NRS), pain medication usage, recovery index (RI-10), return to normal activities (RNA), return to work (RTW), direct and indirect costs (corrected for RTW).

Study description

Background summary

Hysterectomy is one of the most frequently performed major gynaecological surgery in women worldwide. The indication for hysterectomy can be benign or malignant. Most (70%) of the hysterectomies are performed on benign indication. The hysterectomy can be performed using broadly three methods; the vaginal, laparoscopic and abdominal approach. If the vaginal approach is technically not possible due to for example insufficient mobility of the uterus or large uterine size, the laparoscopic route is preferred over the abdominal approach

because it is associated with less pain, less blood loss and a rapid recovery.

Presently, patients remain one night in the hospital after a total laparoscopic hysterectomy and are usually discharged one day after surgery.
To date, a lot of surgical procedures are performed as an ambulatory procedure in order to improve patient recovery and reduce institutional costs.

A recent systematic review shows that when a total laparoscopic hysterectomy is performed on benign indication, when there is a supporting person at home and patients are pre-operatively counseled, the procedure can be performed in a same-day discharge setting. Based on the present literature no conclusions can be drawn whether this leads to a patient satisfaction score.

Study objective

The primary objective of this study is to prove that a Total Laparoscopic Hysterectomy performed with sameday discharge is feasible and that it leads to equal levels of Quality of Life post-operative compared with one night admission.

Study design

Multicentre, randomized controlled trial

Intervention

Same day discharge.

Study burden and risks

Extent of burden:
Participating women will be asked to report their recovery and quality of life at day 1,3, 7 and 6 weeks post-operative.

Risks:
Same day discharge after total laparoscopic hysterectomy has been studies before and seems safe in a relatively health (ASA 1-2) population. There won't be futher risks other than associated with the surgery; perioperative complications (bladder laesion, intestinal perforation, bleeding, infection) and post-operative complications (bleeding, (urinetract-)infection).

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

All consenting women who undergo a total laparoscopic hysterectomy with a benign or premalignant indication
Age 18-65 years
ASA-classification I-II
Dutch speaking
transmen undergoing transgender surgery.

Exclusion criteria

- Women who do not speak Dutch
- Women younger than 18 years
- Women with a history of a midline laparotomy
- Women without a supporting person at home
- Concomitant procedures, other than tubectomy or ovariectomy
- Indication malignant
- Deep invasive endometriosis

- Endtime of surgery past 14.00 o clock
- Patients living further than 1 hr drive from the hospital
- Contra-indications for NSAIDs

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-02-2018
Enrollment:	220
Type:	Actual

Ethics review

Approved WMO Date:	04-12-2017
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	16-01-2018
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	09-08-2018
Application type:	Amendment

Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	07-12-2018
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	26-08-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	31-12-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	12-10-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	08-12-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	01-03-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	04-05-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	19-11-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	01-02-2022
Application type:	Amendment

Review commission: METC Maxima Medisch Centrum (Veldhoven)

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	NL60294.015.17