Same day discHarge aftEr Laparoscopic hysTERectomy (SHELTER trial)

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21121

Source
Nationaal Trial Register

Brief title
SHELTER trial

Health condition

Total laparoscopic hysterectomy, benign indication, discharge.

Totale laparoscopische hysterectomie, benigne indic

Sponsors and support

Primary sponsor: Maxima Medical Centre
Source(s) of monetary or material Support: None

Intervention

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), quality of life and anxiety (EQ-5D) and direct and indirect costs (corrected for RTW).

Study description

Background summary

Previous studies show that performing the total laparoscopic hysterectomy with same day discharge is safe, it is associated with low minor and major complications. Literature shows low numbers of (re) evaluation and (re) admission. Participants fill out short questionnaires 5 different intervals; day of surgery, day 1,3 and 7 and 6 weeks after surgery. The expected benefit is a similar quality life and a decrease in institutional costs.

Study objective

We hypothesize that performing a total laparoscopic hysterectomy with same day discharge is safe and leads to equal levels of patient satisfaction when compared to admittance for 1 night.

Study design

1,3 and 7 days and 6 weeks after surgery.

Intervention

Same-day discharge vs one night admittance after Total Laparoscopic Hysterectomy

Contacts

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Eligibility criteria

Inclusion criteria

Women between 25-65 years of age, ASA classification I-II, who are planned for a TLH with a benign indication.

Exclusion criteria

- Women who do not speak Dutch

- Women younger than 25 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 or atypical hyperplasia of the endometrial tissue

- 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:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-09-2017
Enrollment:	100
Type:	Unknown

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	NL6396
NTR-old	NTR6570

Register	ID
Other	: 60291

Study results

Summary results
None