Vaginal hysterectomy versus vaginal Assisted NOTES Hysterectomy (VANH): a randomised controlled trial

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29386

Source
Nationaal Trial Register

Brief title
VANH

Health condition

Benign indication for hysterectomy

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: not applicable

Intervention

Outcome measures

Primary outcome

The primary objective is the difference in percentage of SDD in both groups.

Secondary outcome

• Complications, severity scored by Clavien-Dindo classification (see attachment 6)
o Injuries to bowel, bladder, ureter, vessels, nerves
o Thrombo-embolic events
o Haematoma requiring surgical intervention
o Haemorrhage requiring transfusion or surgical intervention
o Wound dehiscence requiring surgical intervention
o Wound infections including vaginal vault abscesses
• Treatment related outcomes
o Conversion rate
o Time in operation room (measured from entering the operating theatre until leaving the theatre to the recovery)
o Surgery time (start of incision and end of surgical procedure)
o Blood loss (measured in mL)
o Pain measured in numeric rating scale (NRS) at: 1 hours postoperative, 8 hours postoperative and 24 hours postoperative
o Recovery of pain (measured in NRS) within the first week after surgery
o Use of analgesics (daily use of paracetamol, NSAIDs, opioids)
o Resumption of daily activity
o Hospital readmission within 6 weeks after surgery
o Post-operative pain the first 7 days after surgery (measured on a numeric rating scale (NRS))
• Intended number of salpingectomies in each group
• Number of salpingectomies performed in each group
• Recovery index-10 (RI-10) measured on different moments pre- and post-operative
• Health-related quality of life (EQ-5D-5L questionnaire)
• Costs (including intervention costs, hospital costs, healthcare costs outside the hospital and costs due to loss of productivity; using an adapted version of iMCQ questionnaire) .
• Cost-effectiveness (of VANH versus VH)

Study description

Background summary

Rationale: Natural orifice transluminal endoscopic surgery (NOTES) is a minimal invasive technique using the natural body orifices like stomach, oesophagus, bladder, rectum and vagina to access the human body for surgery. In 2012, the first vaginal NOTES (vNOTES) hysterectomy was performed. Potential benefits of vNOTES hysterectomy, also called the vaginal assisted NOTES hysterectomy (VANH) are no visible scars, less pain and a shorter hospital stay compared with laparoscopic hysterectomy as shown in the HALON trial [1]. Up to now, no studies have compared the vNOTES hysterectomy with vaginal hysterectomy.

Objective: The aim of this study is to compare the vNOTES hysterectomy with the vaginal hysterectomy for same day-discharge (SDD), complications, treatment related outcomes, post-operative recovery, quality of life and cost-effectiveness.

Study design: The study concerns a single-blinded, multicentre, randomised controlled trial.

Study population: Eligible women who fulfil the inclusion criteria and will undergo a hysterectomy for benign indication.

Intervention: The study population will be randomly allocated to the VANH-group, who undergo a vaginal assisted NOTES hysterectomy (intervention group) or the vaginal hysterectomy group (control-group) and the participants will be single blinded. The pre- and postoperative care will be the same for both groups.

Main study parameters/endpoints: Primary outcome is the percentage of patients that underwent the hysterectomy as in SDD setting. A total of 41 patients should be included in the control group and a total of 83 patients in the intervention group, using an enrolment ratio of 1:2, with an alpha of 0.05 and a power of 0.8.
The secondary outcomes are complications, treatment related outcomes, post-operative recovery, quality of life and cost-effectiveness.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
vNOTES is a new surgical technique, but a combination of two existing techniques namely the vaginal hysterectomy and the laparoscopic hysterectomy. Only one randomized controlled trial has been published, comparing the total laparoscopic hysterectomy (TLH) with the VANH, which shows no inferiority of the vNOTES technique compared to a laparoscopy [1]. A recent case series study has been published about the complication rate in VANH. There was a total complication rate in the hysterectomy group of 5.2%, in which 1.4% was intra-operative and 3.8% postoperative [2]. Theoretically it is possible that the VANH causes less intra-operative complications because of an improved view during the procedure. No further literature is known about VH versus VANH. Participants of the study should fill in multiple questionnaires before randomization and postoperative about their general health, pain experience and used analgesics.

Study objective

We hypothesize that patients who underwent a VANH procedure are more often able to be treated in SDD setting.

Study design

First day, first week, first 6 weeks postoperative and first 12 weeks postoperatieve

Intervention

Vaginal NOTES hysterectomy (VANH) versus vaginal hysterectomy

Contacts

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Eligibility criteria

Inclusion criteria

- Written and orally given informed consent
- 18 years and older
- Native Dutch speaker or in control of the Dutch language in speaking and writing
- Indication for hysterectomy for benign indication
- Possible to perform a VH judged by experienced (resident) gynaecologist during gynaecological examination

Exclusion criteria

- Any contra-indication for VH (for example, large uterus myomatosus, not enough descensus, etc) as judged by experienced gynaecologist
- History of more than 1 caesarean section
- History of endometriosis
- History of rectal surgery
- History of pelvic radiation
- Suspected rectovaginal endometriosis
- History of pelvic inflammatory disease, especially prior tubo-ovarian or pouch of Douglas abscess or suspected adhesions due to (ruptured) inflammatory disease (for example ruptured appendicitis)
- Virginity
- Pregnancy
- Indication for anterior or posterior colporrhaphy during the same surgery
- Indication of mid urethral slings
- Uterus myomatosus will not be an exclusion criteria but the surgeon will indicate if it is possible to remove the uterus vaginally.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-05-2021
Enrollment:	124
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	29-04-2021
Application type:	First submission

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	NL9448
Other	METC-Z : METCZ20210035

Study results