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

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The aim of this study is to evaluate same day discharge (SDD), postoperative pain, safety, recovery and cost-effectiveness within 6 weeks after surgery, in woman undergoing two different surgical techniques; VANH or VH

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

Summary

ID

NL-OMON54088

Source
ToetsingOnline

Brief title
VANH-trial

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
removal of uterus, Vaginal hysterectomy

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: geen geldstroom

Intervention

Keyword: Pain, Vaginal assisted NOTES hysterectomy, Vaginal hysterectomy

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) (see attachment 5 and 8).

• Cost-effectiveness (of VANH versus VH)

Study description

Background summary

The hysterectomy is one of the most performed gynaecological surgeries worldwide [2, 3].
In the Netherlands about 14.500 hysterectomies are performed yearly [4]. The most common benign indications to perform a hysterectomy are abnormal uterine bleeding, uterine leiomyomas, endometriosis or adenomyosis, chronic pelvic pain, uterine prolapse, benign ovarian neoplasm, hyperplasia or atypia of the endometrium or cervical dysplasia [5-7].

The four approaches to perform a hysterectomy for benign disease are abdominal hysterectomy (AH), vaginal hysterectomy (VH), laparoscopic hysterectomy (LH) and robotic-assisted hysterectomy (RH) [3, 8].
VH appears to be superior to the AH, resulting in a quicker recovery [5]. The

LH results in a quicker recovery than the AH and VH, but increases the risks of damage to the bladder or ureter [5]. That is why a recent Cochrane review advises to perform a VH when feasible for women undergoing a hysterectomy for a benign indication [5]. When VH is technically not feasible, a LH or AH is performed. LH resulted in more rapid recovery, fewer febrile episodes and less wound complications compared to AH [5]. The RH is not superior compared to the LH and is associated with higher costs [10].

Since the introduction of laparoscopy, the VH and AH decreased and the rate of LH significantly increased between 2002 and 2012 [9]. Performing a LH gives the opportunity to inspect the abdominal cavity and to easily perform an opportunistic salpingectomy compared to VH [10]. An opportunistic salpingectomy during a hysterectomy for benign indication might reduce the overall risk of ovarian cancer [11].
Additionally, patients experience less postoperative pain after a LH compared to a VH and therefore need less post-operative pain medication [10]. Advantages of the VH compared to the LH are a shorter operation duration, no visible scars and a lower chance of dehiscence of the vaginal cuff [10].

In 2004, a novel approach of endoscopic surgery was described, *Natural Orifice Transluminal Endoscopic Surgery (NOTES) by researchers at the John Hopkins University [12]. It is a surgical technique using natural orifices of the body (e.g. mouth, anus, urethra, vagina) to perform scarless surgery [13]. The vaginal approach is called the vNOTES technique. NOTES is an emerging field within minimal access surgery, evolves and presents multiple possibilities for innovation and development. The initial approach was trans gastric, but subsequently, NOTES has been evolved, resulting in trans rectal, trans gastric, transvaginal, and transurethral approaches nowadays [14-16].
In 2012, the first vNOTES hysterectomy, also called vaginal assisted NOTES hysterectomy (VANH) was performed [17]. vNOTES surgery can be used for different indications, for example hysterectomy, adnexectomy, tubectomy or salpingectomy in case of an ectopic pregnancy [18].

In 2018, the first randomised controlled trial (RCT) comparing TLH with VANH in 70 women was published [1]. This HALON trial showed VANH was non-inferior to TLH [1]. Compared to TLH, surgery time was significantly shorter, patients experience less post-operative pain and same day discharge (SDD) was possible in 77% of the women who underwent the VANH compared to 43% after TLH [1]. Besides, the VANH showed less post-operative complications [1].

Except for the HALON trial and two retrospective studies [19, 20] and case-control studies [21, 22] there is little literature about VANH.

No studies have been performed comparing the VH with the VANH. Because the VH is the preferred method to perform a hysterectomy for a benign indication [23], there is a need to compare VH with VANH and to explore the indications to

perform a VANH.

Study objective

The aim of this study is to evaluate same day discharge (SDD), postoperative pain, safety, recovery and cost-effectiveness within 6 weeks after surgery, in woman undergoing two different surgical techniques; VANH or VH

Study design

The design of this study is a single-blind, multicentre, randomised controlled trial (RCT). Eligible patients will be randomised in either the VH group and receive a vaginal hysterectomy or in the VANH-group and the hysterectomy is performed by vaginal assisted NOTES surgery.

Intervention

VANH-hysterectomy

All planned VANH hysterectomies are scheduled in the morning before 12.00u pm. All VANH procedures will be performed by surgeons who have the skills to perform a VANH. This means that the surgeons will be experiences in performing a VANH and must have performed at least 25 VANH independently, as it is demonstrated that he learning curve consists of 25 cases [28].
Elective salpingectomy will be performed after counselling on the outpatient clinic, subsequently on patients request. Pre-operative cefazolin 2 gram and 500 mg metronidazole is administered intravenously.
The patient is placed in lithotomy position. After disinfection and sterile draping, a urinary bladder catheter is inserted into the bladder. At start of the procedure descensus uteri will be classified according to the POPQ-classification.
Access to the peritoneal cavity will be performed similar to vaginal surgery by a circular incision around the cervix, anterior and posterior colpotomy and transsecting the sacro-uterine ligaments.
The vNOTES port (GelPOINT V-Path, Applied Medical) will be placed to get access to the abdominal cavity and a pneumoperitoneum will be created. After positioning in 20o degree Trendelenburg laparoscopic instruments will be introduced (30o laparoscope, a grasping forceps and sealing device through three trocars). The peritoneal cavity and ureters are inspected. The hysterectomy is performed by dissecting from caudally to cranially. The fallopian tubes will be removed elective after counselling in the outpatient clinic and the ovaries will be removed on indication only.
Finally, haemostasis is checked and the vNOTES port and the uterus are removed trans-vaginally and the pneumoperitoneum is deflated. The vaginal cuff will be closed using a running Vicryl-1 suture. The urinary bladder catheter will be

removed directly postoperative.

Study burden and risks

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 with the VANH, which shows no inferiority of the vNOTES technique compared to the TLH. 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. 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.

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

- 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
- Contra-indication for general anaesthesia
- 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-07-2021
Enrollment:	124
Type:	Actual

Ethics review

Approved WMO Date:	23-03-2021
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	16-06-2021
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	07-12-2021
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	28-02-2023
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL76240.096.21