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

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29386

Bron
NTR

Verkorte titel
VANH

Aandoening

Benign indication for hysterectomy

Ondersteuning

Primaire sponsor: Not applicable
Overige ondersteuning: not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Vaginal NOTES hysterectomy (VANH) versus vaginal hysterectomy

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	03-05-2021
Aantal proefpersonen:	124
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	29-04-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9448
Ander register	METC-Z : METCZ20210035

Resultaten