

VAginal NOTES versus Laparoscopic hysterectomy in Uterine Endometrioid Cancer (VALUE-study): a multicentre randomized trial.

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To evaluate the duration of admission, feasibility, patient satisfaction and complication rate of vNOTES hysterectomy with BSO and compare it with laparoscopic hysterectomy with BSO in case of clinical stage 1 low grade endometrial cancer.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON51251

Source

ToetsingOnline

Brief title

VALUE study

Condition

- Reproductive neoplasms female malignant and unspecified
- Uterine, pelvic and broad ligament disorders
- Obstetric and gynaecological therapeutic procedures

Synonym

uterine cancer; endometrioid adenocarcinoma of the endometrium

Research involving

Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: afhankelijk van lopende subsidie aanvraag bij ZonMw en als deze niet wordt gehonoreerd dan wordt er een aanvraag bij het KWF ingediend, Mocht er geen externe financiering mogelijk zijn dan nog zal de studie plaats vinden. De extra kosten worden gemaakt door de inzet van personeel; welke bij ontbrekende financiering worden gecompenseerd met eigen inzet. De kosten voor materialen zijn voor rekening van de deelnemende ziekenhuizen en zullen ook niet in geval van financiering worden vergoed.

Intervention

Keyword: endometrial carcinoma, hysterectomy, vNOTES

Outcome measures

Primary outcome

The primary outcome is percentage of women discharged on the same day as the hysterectomy (day 0).

We calculated a sample size of 147 women assuming a 30% same day discharge difference with an alpha of 0.05 and a power of 90%. We plan to perform a follow up study of this trial to proof oncological safety of the procedure.

Secondary outcome

Secondary outcomes are removal of uterus via allocated technique, major complications, minor complications, operating time, conversion rate, blood loss, hospital stay, usage of analgesics, pain scores, costs and quality of life (QoL).

Study description

Background summary

The treatment of clinical stage 1 low-grade endometrial cancer consists of hysterectomy and bilateral salpingo-oophorectomy (BSO). Nowadays total laparoscopic hysterectomy (TLH) with BSO is the principal mode of surgery in these cases, resulting in shorter hospital stay, less pain and earlier recovery after surgery when compared to laparotomy^{1,2}. Vaginal Natural Orifice Transluminal Endoscopic Surgery (vNOTES) is a new surgical endoscopic technique that can be applied to perform a hysterectomy. Recent research has demonstrated that vNOTES hysterectomy leads to a shorter hospital stay, lower self-reported VAS pain scores and less postoperative use of analgesics compared to laparoscopic hysterectomy³.

Study objective

To evaluate the duration of admission, feasibility, patient satisfaction and complication rate of vNOTES hysterectomy with BSO and compare it with laparoscopic hysterectomy with BSO in case of clinical stage 1 low grade endometrial cancer.

Study design

Multicentre randomized controlled trial

Intervention

Patients are randomized between hysterectomy and bilateral salpingo-oophorectomy with vNOTES or conventional laparoscopy.

Study burden and risks

Standard of care in women diagnosed with clinical stage 1 low-grade endometrial cancer is to perform a chest X-ray. If there are no signs of metastatic disease and no advanced stage patients are planned for hysterectomy and BSO. Patients with the indication of laparoscopic hysterectomy with BSO for endometrial cancer or atypical hyperplasia and no contraindications for vNOTES hysterectomy are asked if they want to participate in this study. At this moment, TLH with BSO is the standard surgical technique in these patients. All included women will be randomized between vNOTES or laparoscopic hysterectomy with BSO in a 2:1 ratio. Standard postoperative contact by phone or out patient department visits at 2 and 6 weeks will be planned and patients will be asked to complete QoL questionnaires after 1 and 2 days, 1,4,6 and 12 weeks. Studies have shown that vNOTES hysterectomy is associated with a shorter hospital stay, less pain, less usage of analgesics, no scars and a quicker resumption to daily activity and no higher risk of complications when compared to laparoscopic hysterectomy.

Permission will be asked to consult the national pathology database (PALGA) and the database of the Dutch Integrated Cancer Centre (IKNL) up to 5 years postoperative to ensure oncological follow up. Besides this follow-up we plan to perform a follow up study of all patients with low-grade endometrial cancer treated by vNOTES hysterectomy and BSO to ensure oncologic safety.

It is expected that patients treated with vNOTES will have a shorter hospital stay without increased risk of major complications and have a less pain, less usage of analgesics and a quicker resumption to daily activity.

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

clinical stage 1 endometrial cancer

Exclusion criteria

non-endometrioid endometrial cancer, high stage disease

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	20-05-2022
Enrollment:	147
Type:	Actual

Medical products/devices used

Generic name:	GelPOINT ® V-path
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	21-05-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 05-03-2024

Application type: Amendment

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24941

Source: NTR

Title:

In other registers

Register	ID
CCMO	NL77309.100.21
OMON	NL-OMON24941