VALUE study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24941

Source
NTR

Brief title
VALUE study

Health condition

Low grade endometrial cancer

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

percentage of patients treated in day-care setting

Secondary outcome

Major complications, severity scored by Clavien-Dindo classification
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 requiring surgical intervention or admission
Minor complications
o urinary tract infections in the first 2 weeks postoperative for which antibiotics are started
o surgical site infections; excluding vaginal vault abscesses that do not require surgical intervention but are treated expectantly
or with antibiotics.
Treatment related outcomes
o conversion rate (number of vNOTES cases that were converted to TLH)
o operating time (measured from the start of the inscision until end of surgery)
o time in operation room (measured from the entry and departure of the patients in the OR)
o successful resection of adnexa
o total amount of CO2 used during procedure. (measured in litres CO2)
o blood loss (measured in millilitres)
o hospital stay (measured in hours)
o usage of analgesics (usage and amount of paracetamol, NSAIDs or opioids)
o resumption of daily activity (scored by return to daily activity questionnaire)
o hospital readmission within 6 weeks after surgery
o post-operative pain the first 48 hours after surgery (measured on a numeric rating scale)
Quality of life up to 12 weeks
o QoR-40 questionnaire (day 1,2 and 7)
o Recovery-Index 10 (week 1,4,6, 12)

Study description

Background summary

Rationale: 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. 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 hysterectomy.

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

Study design: Multicentre randomized controlled trial

Study population: Women aged over 18 years old with a clinical stage 1 low-grade (grade 1 or 2) endometrioid adenocarcinoma of the endometrium or atypical hyperplasia of the endometrium who are planned for hysterectomy and bilateral salpingo-oophorectomy.

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

Main study parameters/endpoints: The primary outcome is percentage of women discharged on the same day as the hysterectomy (day 0). 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). 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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study objective

vNOTES hysterectomy will lead to shorter duration of admission

Study design

12 weeks follow up

Intervention

vNOTES hysterectomy

Contacts

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Eligibility criteria

Inclusion criteria

- 18 years and older
- Written and orally given informed consent
- Patients with a histologically confirmed low grade endometrial carcinoma with no signs of progressive or metastatic disease
- Patients with atypical hyperplasia
- Clinical assessment of feasibility to perform laparoscopic or vNOTES hysterectomy with BSO

Exclusion criteria

Patients with high grade endometrial cancer
Patients with advanced stage low grade endometrial cancer
Patients unfit for surgery
Significant language barrier
Contraindication for laparoscopic or vNOTES hysterectomy such as:
• History of rectal surgery
• History of pelvic radiation
• History of pelvic inflammatory disease, especially prior tubo-ovarian or pouch of Douglas abscess

• 2 or more caesarean sections in history

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2021
Enrollment:	147
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 51251
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9395
CCMO	NL77309.100.21
OMON	NL-OMON51251

Study results