

To compare the quality of life after removal of the uterus by means of open (abdominal) or minimally invasive (laparoscopic) approach

Submission date 17/09/2011	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 09/11/2011	Overall study status Completed	☐ Protocol
Last Edited 21/05/2015	Condition category Urological and Genital Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Background and study aims

Hysterectomy (removal of the uterus) is the most frequently performed gynecological operation. In abdominal hysterectomy, the uterus is removed through a 10-14 cm cut (incision) in the abdomen. In laparoscopic hysterectomy, small instruments and a camera are introduced into the abdomen through 3-4 small incisions of less than 1 cm each. Using these instruments, the uterus can be released from the surrounding tissues and blood supply and can be removed through the vagina. Laparoscopic hysterectomy might be better for patients in terms of pain, hospital stay, blood loss and cosmetic results. We want to find out if there are benefits 4 years after surgery.

Who can participate?

Women scheduled for hysterectomy for benign (non-cancerous) disease.

What does the study involve?

The participants were randomly allocated to undergo either abdominal or laparoscopic hysterectomy. Operation time, blood loss, pain and number of days in the hospital were recorded. Participants were asked to fill in a quality of life questionnaire 2, 4, 6 and 12 weeks and 4 years after the surgery.

What are the possible benefits and risks of participating?

This study will help us find out whether there is any long-term advantage of laparoscopic hysterectomy over abdominal hysterectomy.

Where is the study run from?

Maxima Medical Center in Veldhoven, Netherlands.

When is the study starting and how long is it expected to run for?

The study started in 2002 and ran for about 2 years.

Who is funding the study?
Maxima Medical Center, Netherlands.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MMC2112

Study information

Scientific Title
A randomized trial to compare the quality of life after removal of the uterus by means of open (abdominal) or minimally invasive (laparoscopic) approach

Study objectives
It is expected that quality of life is better after laparoscopic than after abdominal hysterectomy. This study with a long term follow-up of 4 years was conducted to evaluate whether any long term differences would remain between the two approached.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Medical Ethical Committee of the Maxima Medical Centre Veldhoven, 25/07/2002, ref: METC-MMC 0217

Primary study design
Interventional

Study design

Single-centre randomized controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Benign gynecological diseases such as bleeding disorders or dysmenorrhoea

Interventions

Abdominal versus laparoscopic hysterectomy.

Abdominal hysterectomies were performed through a transverse (Pfannenstiel) incision and surgery was carried by means of the standard extrafascial technique.

Laparoscopic hysterectomies were all intentionally total laparoscopic hysterectomy. This means that the whole procedure was carried out laparoscopically, except the removal of the uterus, which was carried out via the vagina.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Quality of life, measured 2, 4, 6 and 12 weeks post surgery by means of the Short Form 36 health survey

Key secondary outcome(s)

1. Operation time
2. Blood loss
3. Hospital stay

Completion date

01/07/2009

Eligibility**Key inclusion criteria**

Patients scheduled for hysterectomy for benign conditions in which a vaginal hysterectomy was not possible

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Size of the uterus greater than 18 weeks gestation
2. A suspicion of malignancy
3. A previous lower midline incision
4. The need for simultaneous interventions like prolapse repair
5. Inability to speak Dutch
6. Furthermore, patients using antidepressant drugs or with a history of psychiatric disease or other severe medical issues

Date of first enrolment

01/08/2002

Date of final enrolment

01/07/2009

Locations**Countries of recruitment**

Netherlands

Study participating centre

Geert Grooteplein 10

Nijmegen

Netherlands

6500 HB

Sponsor information**Organisation**

Maxima Medical Center (Netherlands)

ROR

<https://ror.org/02x6rcb77>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2007		Yes	No
Results article	results	01/01/2012		Yes	No