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# 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

**Registration date**
09/11/2011

**Overall study status**
Completed

**Last Edited**
21/05/2015

**Condition category**
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] 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?
Dr Th. E. Nieboer
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# Contact information

### Type(s)
Scientific

### Contact name
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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

### Study design
Single-centre randomized controlled trial

### Primary study design
Interventional

### 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
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6500 HB

## Sponsor information

### Organisation
Maxima Medical Center (Netherlands)

### ROR
https://ror.org/02x6rcb77

## Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name

Maxima Medical Center (Netherlands)

# 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |