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

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

## 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 b.nieboer@obgyn.umcn.nl

## Contact information

#### Type(s)

Scientific

#### Contact name

Dr Theodoor E Nieboer

#### Contact details

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## Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

#### 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 measure

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

## Secondary outcome measures

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

## Overall study start date

01/08/2002

### 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** 

#### Age group

Adult

#### Sex

Female

### Target number of participants

59

#### 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)

#### Sponsor details

Postbus 7777 Veldhoven Netherlands 5500 MB

#### Sponsor type

Hospital/treatment centre

#### **ROR**

https://ror.org/02x6rcb77

## Funder(s)

### Funder type

Hospital/treatment centre

#### **Funder Name**

Maxima Medical Center (Netherlands)

## **Results and Publications**

## Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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