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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?
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Contact information

Type(s)
Scientific

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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