

A randomised study of the postoperative quality of life: laparoscopic UTerine Artery Clipping versus laparoscopy-assisted vaginal hysterectomy for the management of symptomatic uterine fibroids

Submission date 29/05/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/06/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/07/2009	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SNUHOBGY001

Study information

Scientific Title

Acronym

UTAC trial

Study objectives

Laparoscopic Uterine Artery Clipping (LUAC) may be an alternative treatment for the improvement of postoperative Quality Of Life (QOL) in patients with symptomatic uterine fibroids, compared with Laparoscopy-Assisted Vaginal Hysterectomy (LAVH).

Ethics approval required

Old ethics approval format

Ethics approval(s)

The ethical committee of Seoul National University College of Medicine and Seoul National University Hospital approved the protocol for this study on the 9th May 2007 (IRB no.: H-0704-032-205).

Study design

Randomised controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Uterine fibroids

Interventions

Group 1: treated with Laparoscopic Uterine Artery Clipping (LUAC)

Group 2: treated with Laparoscopy-Assisted Vaginal Hysterectomy (LAVH)

After both treatments, we will follow up the enrolled patients in this trial during one year. We will compare preoperative and postoperative (after one year) QOLs between two groups.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Postoperative quality of life until one year after surgical treatment using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer patients (EORTC QLQ-C30) version 3.0.

Secondary outcome measures

1. Volume reduction of uterus, ovary, and fibroids in Group 1: Volume (cm³) = length (cm) X width (cm) X depth (cm) X 0.5233, measured every three months till one year
2. Improvement of subjective symptoms in both groups: 11 point symptom score, ranging from -5 (markedly worse) to +5 (markedly better), checked after one year postoperatively
3. Evaluation of postoperative menorrhagia in Group 1: using a simple visual assessment technique, measured monthly using the recording sheet including simple visual assessment technique by herself. After one year postoperatively, we will collect the recording sheets from the patients and analyze the data.

Overall study start date

01/05/2007

Completion date

30/06/2009

Eligibility

Key inclusion criteria

1. Aged greater than or equal to 40 years old
2. Patients who do not want conception any more
3. Patients who agree to this study with informed consent
4. More than 2 cm sized uterine fibroids on Ultrasonography (USG)
5. Uterine fibroids with symptoms such as menorrhagia, dysmenorrhoea, lower abdominal discomfort or pain, lower back pain, urologic problems (dysuria, frequency, etc.,)
6. Patients without underlying disease affecting QOL
7. At least six months interval after last medication, if patients have been treated with Gonadotropin-Releasing Hormone (GnRH) agonists

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Group 1 (LUAC): 30 patients; Group 2 (LAVH): 30 patients

Key exclusion criteria

1. Aged less than 40 years old
2. Patients with subserosal pedunculated fibroid
3. Pregnant women
4. Patients with pelvic inflammatory disease developed within one month
5. Patients with contraindication of surgical treatment
6. Patients with previous history of myomectomy, hysterectomy, myolysis, uterine artery embolisation
7. Less than six months interval after last medication, if patients have been treated with GnRH agonist
8. Patients with underlying disease affecting QOL

Date of first enrolment

01/05/2007

Date of final enrolment

30/06/2009

Locations

Countries of recruitment

Korea, South

Study participating centre

Department of Obstetrics and Gynecology and Cancer Research Institute

Seoul

Korea, South

110-744

Sponsor information

Organisation

Seoul National University (South Korea)

Sponsor details

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Sponsor type
University/education

Website
<http://www.snu.ac.kr/>

ROR
<https://ror.org/04h9pn542>

Funder(s)

Funder type
University/education

Funder Name
Seoul National University (South Korea) - College of Medicine, Department of Obstetrics and Gynaecology

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?
Protocol article	protocol	29/01/2009		Yes	No