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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	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/06/2007	**Overall study status** Completed	
Last Edited 20/07/2009	**Condition category** Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 (cm^3) = 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
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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