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Hysteroscopic removal of intra-uterine disorders: a comparative study of learning electrosurgical versus mechanical techniques

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/09/2008	Urological and Genital Diseases	[ ] Record updated in last year

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

NTR249

Study information

Scientific Title

Acronym
SHAVER trial

Study objectives
To compare the standard hysteroscopic electrosurgical resection technique with the new hysteroscopic morcellator technique in a residency program to assess the learning curve effect of both techniques.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Multicentre, randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pedunculated and sessile intra-uterine disorders

Interventions
1. Electrosurgical resection using the hystero-resectoscope (control)
2. Mechanical morcellating technique using the hysteroscopic morcellator (with saline irrigation)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Parameters for easiness of use:
1. Operating-time
2. Amount of intravasation
3. Number of insertions of the instrument
4. Number of conversions to other techniques
5. Completeness of removal and subjective score of the surgeon (resident in training) and supervisor-trainer by Visual Analogue Scales (range poor 0 and excellent 10)

Secondary outcome measures
1. Complications (perforation, bleeding, transurethral resection (TUR) syndrome, etc.)
2. Failure

Overall study start date
01/01/2005

Completion date
01/04/2006

Eligibility

Key inclusion criteria
All patients with pedunculated and sessile intra-uterine disorders with an indication for removal (endometrial polyps and submucous myomas type 0 and I)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
60

Key exclusion criteria
1. Non-pedunculated disorders (type II myomas)
2. Suspicion of malignancy
3. Contra-indication for hysteroscopic surgery

Date of first enrolment
01/01/2005

Date of final enrolment
01/04/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Centre
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (Netherlands)

Sponsor details
Albinusdreef 2
P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type
University/education

Website
http://www.lumc.nl/

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leiden University Medical Centre (LUMC) (The 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