

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

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

Protocol serial number
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

Primary study design

Interventional

Study design

Multicentre, randomised, active controlled, parallel group trial

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

ROR

<https://ror.org/027bh9e22>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Leiden University Medical Centre (LUMC) (The Netherlands)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration