

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/09/2008	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

Study information

Scientific Title

Acronym

SHAYER 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