Pre-ablation endometrial preparation: a comparison between GnRH agonist leuporelin and GnRH antagonist Cetrorelix. A Randomised Controlled Trial.

Submission date	Recruitment status No longer recruiting	Prospectively registered		
30/09/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/09/2005	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
01/10/2008	Surgery			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number N0375157911

Study information

Scientific Title

Study objectives

To compare the effects of GnRH antagonist Cetrorelix (Cetrocide) and GnRH agonist Leuprorelin (Prostap SR) injections for preoperative endometrial preparation, prior to Transcervical Endometrial Resection (TCRE)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Surgery: Transcervical Endometrial Resection (TCRE)

Interventions

Comparison between GnRH agonist leuporelin and GnRH antagonist Cetrorelix.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

- 1. Endometrial thickness as measured on trans-vaginal ultrasound (sagittal plane) on the day of operation
- 2. Histological assessment of "endometrial chippings"
- 3. Comparison of side effect profile
- 4. Operative difficulties
- 5. Overall patient satisfaction

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/12/2005

Eligibility

Key inclusion criteria

100 eligible women will be identified from those already on the waiting list for Transcervical Endometrial Resection (TCRE).

They will be suitable candidates for the procedure and those with submucous fibroid will not be excluded.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

- 1. Women on hormonal medications within last 3 months
- 2. Uterine size more than 12 weeks
- 3. Previous TCRE

Date of first enrolment

31/10/2003

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Shrewsbury & Telford Hospital NHS Trust
Shrewsbury
United Kingdom
SY3 8XQ

Sponsor information

Funder(s)

Funder type

Government

Funder Name

Shrewsbury and Telford Research and Development Consortium (UK)

Results and Publications

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?
Results article	results	01/09/2008		Yes	No