ISRCTN14156709 https://doi.org/10.1186/ISRCTN14156709

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

Submission date
30/09/2005

Recruitment status
No longer recruiting

Registration date
30/09/2005

Overall study status
Completed

Last Edited
01/10/2008

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr B Bentick

Contact details
Shrewsbury & Telford Hospital NHS Trust
Royal Shrewsbury Hospital
Mytton Oak Road
Shrewsbury
United Kingdom
SY3 8XQ
+44 (0)1743 261142
Bernie.Bentick@rsh.nhs.uk

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

Primary study design
Interventional

Study design
Randomised controlled trial

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

Organisation

Department of Health

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