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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
31/10/2003

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
100

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

England

United Kingdom

Study participating centre
Shrewsbury & Telford Hospital NHS Trust
Shrewsbury
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Sponsor information

Organisation
Department of Health

Sponsor details
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Shrewsbury and Telford Research and Development Consortium (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2008		Yes	No