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A prospective randomised controlled trial to compare laparoscopic ovarian diathermy with clomiphene citrate as a first line treatment of anovulatory infertiliity in patients with polycystic ovarian syndrome

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
12/09/2011

Condition category
Nutritional, Metabolic, Endocrine

[_] 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
NCT00220545

Secondary identifying numbers
N0059108266

Study information

Scientific Title

Study objectives
Laparoscopic ovarian diathermy (LOD) is currently widely used as an effective second line treatment for induction of ovulation in anovular infertile women with polycyctic ovarian syndrome (PCOS) after failure of a course of clomiphene citrate (CC). CC treatment is associated with significant drawbacks including a lower than expected pregnancy rate, high miscarriage rate (about 40%) and increased incidence of multiple pregnancies (10%). These well-documented drawbacks to CC create equipoise between CC and LOD. The aim of this study is to test the hypothesis that LOD used as a first line treatment in these cases will generate better pregnancy rates with fewer multiple pregnancies and higher live birth rate than treatment with clomiphene citrate.

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Polycystic ovarian syndrome (PCOS)

Interventions
Compare laparoscopic ovarian diathermy with clomiphene citrate as a first line treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Live birth rate

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2001

Completion date
01/09/2004

Eligibility

Key inclusion criteria
264 infertile women with PCOS

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
264

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/10/2001

Date of final enrolment
01/09/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Sheffield
Sheffield
United Kingdom
S10 2SF

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Charity

Funder Name
UK charity

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	01/01/2009		Yes	No
Results article	results on anti-Mullerian hormone measurement	01/11/2009		Yes	No