ISRCTN54264327 https://doi.org/10.1186/ISRCTN54264327

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

ClinicalTrials.gov (NCT)
NCT00220545

Protocol serial number
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

Study type(s)
Treatment

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(s)
Live birth rate

Key secondary outcome(s))

Not provided at time of registration

Completion date
01/09/2004

Eligibility

Key inclusion criteria
264 infertile women with PCOS

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Charity

Funder Name
UK charity

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