

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

Submission date

12/09/2003

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

12/09/2003

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

12/09/2011

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Bill Ledger

Contact details

University of Sheffield

OGN & Midwifery

Jessop Wing

Sheffield

United Kingdom

S10 2SF

+44 (0)114 226 8317

w.ledger@sheffield.ac.uk

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 polycystic 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

Primary study design

Interventional

Study design

Randomised controlled trial

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