

# 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**

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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 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

**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?
<a href="#">Results article</a>	results	01/01/2009		Yes	No
<a href="#">Results article</a>	results on anti-Mullerian hormone measurement	01/11/2009		Yes	No