# Effectiveness of ovarian suspension in preventing post-operative ovarian adhesions in women with pelvic endometriosis

Submission date

Recruitment status

30/09/2004

No longer recruiting

[X] Protocol

Registration date

Overall study status

Statistical analysis plan

[X] Prospectively registered

30/09/2004

Completed

[X] Results

Last Edited 01/09/2014 Condition category

Surgery

[ ] Individual participant data

Plain English summary of protocol

Not provided at time of registration

# Contact information

Type(s)

Scientific

Contact name

Dr William Hoo

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

# Secondary identifying numbers

N0263139724

# Study information

#### Scientific Title

Effectiveness of ovarian suspension in preventing post-operative ovarian adhesions in women with pelvic endometriosis: a randomised controlled trial

### **Study objectives**

Added 03/11/2010:

Suspending the ovaries to the anterior abdominal wall (ovarian suspension) after laparoscopic surgery for severe pelvic endometriosis for 36 to 48 hours will reduce the incidence of post-operative ovarian adhesion.

No information provided at time of registration.

Please note that as of 03/11/2010 this record has been extensively updated, with further revisions and clarifications to the record on 12/11/2010. Due to issues with recruitment the trial, originally planned for 19/11/2003 to 01/11/2008, was stopped and underwent protocol and ethics amendments. Details of these amendments can be found in the relevant field with one of the above update dates.

### Ethics approval required

Old ethics approval format

# Ethics approval(s)

The Medical Ethical Committees of the University College Hospital, London approved amendments to the protocol on 08/04/2009 and 29/04/2010, ref: 03/0279

# 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

Not available in web format, please use contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

#### Endometriosis; Laparoscopic surgery

#### **Interventions**

Current information as of 12/11/2010:

Ovarian suspension following laparoscopic excision of severe pelvic endometriosis: Patients will be randomised at the time of surgery to have either their left or right ovary suspended. The other ovary will be allowed to fall back into the pelvis, therefore acting as a control within the same patient.

Ovarian suspension will be for at least 36 hours. An extra 12 hours is allowed for practical reasons in situations where sutures may needs to be removed in the middle of the night. There will be no comparision between variations in the duration of suspension.

Initial information at time of registration:

- 1. Ovary suspension
- 2. Non ovary suspension

#### Intervention Type

Procedure/Surgery

#### Phase

Not Applicable

#### Primary outcome measure

Current information as of 03/11/2010:

Presence of ovarian adhesions as assessed by pelvic ultrasound scan, 3 months post-operatively.

Initial information at time of registration:

The grade of peri-ovarian adhesion with and without ovarian suspension.

# Secondary outcome measures

Current information as of 03/11/2010:

Presence, intensity and site of postoperative pain

Initial information at time of registration:

Difference in pain between the two sides of the abdomen in the first three post-operative days.

#### Overall study start date

01/10/2008

#### Completion date

01/06/2011

# **Eligibility**

#### Key inclusion criteria

Added 03/11/2010:

- 1. Age 19 or older
- 2. Internal scan not contraindicated
- 3. Severe pelvic endometriosis involving rectovaginal space and/or both ovaries
- 4. Fertility preserving surgery

Information not provided at time of registration

### Participant type(s)

**Patient** 

### Age group

Adult

#### Sex

**Female** 

### Target number of participants

Added 03/11/2010: 50 patients (at time of registration: 20 patients)

#### Key exclusion criteria

Added 03/11/2010:

- 1. Mild or moderate endometriosis
- 2. Incomplete resection of pelvic endometriosis (cyst drainage pre-IVF treatment or planned two-stage operations)
- 3. Patients undergoing radical surgery for endometriosis including oophrectomies or hysterectomies
- 4. Complications requiring ileostomies or open surgery

Information not provided at time of registration

#### Date of first enrolment

01/10/2008

#### Date of final enrolment

01/06/2011

# Locations

# Countries of recruitment

England

United Kingdom

# Study participating centre

Clinic 3

London United Kingdom NW1 2BU

# Sponsor information

# Organisation

Department of Health

#### Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

### Sponsor type

Government

#### Website

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

# Funder(s)

### Funder type

Hospital/treatment centre

#### Funder Name

University College London Hospitals NHS Trust (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?
Protocol article	protocol	11/05/2011		Yes	No
Results article	results	01/04/2014		Yes	No