ISRCTN24242218 https://doi.org/10.1186/ISRCTN24242218

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

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 01/09/2014	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

Study participating centre
Clinic 3
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University College London Hospitals NHS Trust (UK)

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	01/04/2014		Yes	No
Protocol article	protocol	11/05/2011		Yes	No