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Randomised controlled trial of laparoscopic adhesiolysis for women with chronic pelvic pain

Submission date 08/09/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/12/2005	**Overall study status** Completed	
Last Edited 14/03/2014	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
STH14212

Study information

Scientific Title

Study objectives
Adhesiolysis leads to the improvement of pain and quality of life.

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

Health condition(s) or problem(s) studied
Adhesions and chronic pelvic pain

Interventions
Operative laparoscopy or diagnostic laparoscopy.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
1. Pain (visual analogue scale [VAS])
2. Quality of life (SF 36)
3. Medications requirement

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2006

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Age over 18 years
2. Chronic pelvic pain over 6 months duration

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
200

Key exclusion criteria
1. Pregnancy
2. Malignancy
3. Acute pathology that neeeds immediate treatment
4. On CNS stimulant/medications for psychiatric illness

Date of first enrolment
01/01/2006

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Level 4
Sheffield
United Kingdom
S10 2SF

Sponsor information

Organisation
Sheffield Hospitals Charitable Trust (UK)

Sponsor details
5 Old Fulwood Road
Sheffield
United Kingdom
S10 3TG

Sponsor type
Charity

Funder(s)

Funder type
Charity

Funder Name
Sheffield Hospitals Charitable Trust

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?

Abstract results	results (meeting abstract)	01/06/2013	No	No
Results article	results	04/03/2014	Yes	No