ISRCTN77645288 https://doi.org/10.1186/ISRCTN77645288

A multicentre randomised controlled trial assessing the benefit of icodextrin solution on pelvic pain and quality of life in patients having surgery to adhesions

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 07/07/2017	**Condition category** Respiratory	

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
N0283122696

Study information

Scientific Title
A multicentre randomised controlled trial assessing the benefit of icodextrin solution on pelvic pain and quality of life in patients having surgery to adhesions

Study objectives
We hypothesise that the infusion of 1000 ml 4% icodextrin solution into the abdomen at the end of adhesiolysis for abdomino-pelvic adhesions will result in improvements in chronic pain scores and quality of life that is superior to heparinised normal saline.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre single-blinded 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
Respiratory: Pain

Interventions
1. Icodextrin
2. Heparinised saline

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Icodextrin

Primary outcome measure
Chronic pain measured before and 18 weeks after surgery on a visual analogue scale

Secondary outcome measures
1. Separate questions for dysmenorrhoea (pain with periods), dyspareunia (pain on intercourse), and dyschezia (pain on defecation)
2. Quality of life will be measured with an EQ-5D questionnaire (EuroQol) before and 18 weeks after the procedure

Overall study start date
01/06/2002

Completion date
01/06/2003

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
250 (125 patients in each treatment arm)

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/06/2002

Date of final enrolment
01/06/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Worthing & Southlands Hospitals NHS Trust
Worthing
United Kingdom
BN11 2DH

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
Government

Funder Name
Sussex NHS Research Consortium (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