

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
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 07/07/2017	Condition category Respiratory	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

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

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

01/06/2003

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Worthing & Southlands Hospitals NHS Trust

Worthing

United Kingdom

BN11 2DH

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Sussex NHS Research Consortium (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration