

The effect of cryoanalgesia on pain perception during infiltration of local anaesthetic agents: a randomised double blind controlled trial

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/02/2008	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0515154546

Study information

Scientific Title

Study objectives

Does cryoanalgesia used prior to injection of local anaesthetic agent, reduce pain perception during infiltration of the agents?

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)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Signs and Symptoms: Pain

Interventions

Patients from one-stop hernia clinic will be given the research protocol information sheet on arrival (i.e. one hour prior to surgery). Surgeons will explain the research and the operation and obtain an informed consent, for both the operation and entry into the trial. Surgeons will answer any and every patient query regarding the trial and the operation. Patients will have the right to withdraw from the trial at any point without explanation. Patients will be randomised alternately into:

1. The control group
2. The trial group

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Level of pain perception during infiltration of local anaesthetic agents and the operative procedure

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/2004

Completion date

30/08/2006

Eligibility

Key inclusion criteria

All patients coming for hernia repairs under local anaesthetic in 'One-Stop Hernia Clinic' at ACAD will be requested to enter into trial on the day of arrival. Patient will be give complete information regarding the trial and will be explained that they are free no to enter if the so wish. Approximately 50 patients in each group.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

100

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/10/2004

Date of final enrolment

30/08/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Surgery
Harrow
United Kingdom
HA1 3UJ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type
Government

Funder Name
North West 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?
Results article	results	01/07/2007		Yes	No