

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	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 20/02/2008	Condition category Signs and Symptoms	☐ 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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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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 given complete information regarding the trial and will be explained that they are free not to enter if they so wish. Approximately 50 patients in each group.

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

01/10/2004

Date of final enrolment

30/08/2006

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre**Department of Surgery**

Harrow

United Kingdom

HA1 3UJ

Sponsor information**Organisation**

Department of Health

Funder(s)

Funder type

Government

Funder Name

North West 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	01/07/2007		Yes	No