ISRCTN58354123 https://doi.org/10.1186/ISRCTN58354123

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

Registration date
30/09/2005

Overall study status
Completed

Last Edited
20/02/2008

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Raj Bhutiani

Contact details
Department of Surgery
North West London Hospitals NHS Trust
Northwick Park Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

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 inflitration 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