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A randomised controlled trial of pain experienced during the injection of intralesional steroid with or without prior cryoanalgesia

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 25/04/2012	**Condition category** Skin and Connective Tissue Diseases	

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
N0205134575

Study information

Scientific Title

Study objectives
Does cryoanalgesia reduce the pain associated with intralesional steroid injection? Cryoanalgesia is a well-documented technique for reducing pain preceding local anaesthetics by many years. However, the introduction of new anaesthetics and techniques, has reduced its use. Patients worry about steroid injections and one possibility is that of the pain caused by the injections. The aim of our study is to compare the pain experienced on steroid injection of the keloid scar, with and without prior cryoanalgesia.

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Skin and Connective Tissue Diseases: Keloid scars

Interventions
A randomised prospective clinical trial.
Subjects: patients who are scheduled for intralesional injection of their keloid scars
Methods: patients to be randomised into two groups to either receive application of ice pack or not, prior to steroid injection
Results: does cryoanalgesia reduce the pain experienced on administration of the steroid injection?

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
A visual analogue scale will be completed to and after the steroid injection and the subjects will be asked to rate the pain experienced. Pain scores will then be compared between the groups.

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/04/2004

Eligibility

Key inclusion criteria
Patients over the age of 18 who are scheduled to receive intralesional steroid injections as part of their treatment for keloid scarring. This will include patients within the Greater London Area.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/10/2003

Date of final enrolment
01/04/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Plastic Surgery
London
United Kingdom
E1 1BB

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Barts and The London 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	01/12/2003		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes