

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	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/04/2012	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/2003

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

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre

Plastic Surgery

London

United Kingdom

E1 1BB

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Barts and The London 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	01/12/2003		Yes	No