

Randomised placebo controlled cross-over trial of topical opioids in the management of analgesia in leg ulcers

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 14/10/2015	Condition category Skin and Connective Tissue Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

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

Protocol serial number

N0295122854

Study information

Scientific Title

Randomised placebo controlled cross-over trial of topical opioids in the management of analgesia in leg ulcers

Study objectives

Does topical morphine reduce the systematic requirement for analgesia in the treatment of pain from chronic leg ulcers?

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

Prospective randomised controlled cross-over trial with questionnaire and interviews. Topical opioids versus placebo.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

PRN (pro re nata - as needed) and regular analgesia requirement over preceding 24 h. Daily pain score and questionnaire regarding side-effects.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2004

Eligibility**Key inclusion criteria**

20 Patients with chronic painful leg ulcers, from all inpatients at the Walsgrave Hospital (powered to give 75-80% preference rate of either active or placebo gel).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/06/2003

Date of final enrolment

31/12/2004

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Department of Dermatology

Coventry

United Kingdom

CV2 2DX

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

University Hospitals Coventry and Warwickshire NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration