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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 [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 14/10/2015	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

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 measure

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2003

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
20

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
England

United Kingdom

Study participating centre

Department of Dermatology
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospitals Coventry and Warwickshire 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