ISRCTN76288165 https://doi.org/10.1186/ISRCTN76288165

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Joanne Deacon

Contact details
Department of Dermatology
UHCW NHS Trust
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

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

Study design
Randomised controlled trial

Primary study design
Interventional

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes