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The influence of venous impulse foot pumps on pin tract infections: A prospective randomised controlled trial

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
30/03/2020	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr B Venkateswaran

Contact details
Orthopaedics
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ
+44 (0)1274 734744 bleep 446
abc@email.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0050111063

Study information

Scientific Title
The influence of venous impulse foot pumps on pin tract infections: A prospective randomised controlled trial

Study objectives
Does the use of foot pumps reduce:
1. The incidence of pin tract sepsis?
2. The morbidity of established infection?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
A prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Infections and Infestations: Pin tract infections

Interventions
A prospective randomised controlled trial/case note review. Randomise patients with external fixators to two groups - 1. with and 2. without foot pump. A minimum period of 72 h of foot pump usage is aimed at to see any changes. As well as this, both groups will have the normal routine of treatment and prevention of infection at the pin sites. This is already in place. They are followed up till their usual first clinic visit to observe effect on the pin site.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Establishment of status of pin site as infected or not infected on clinical examination both at discharge and first clinic visit.

Secondary outcome measures
Not provided at time of registration

Overall study start date
27/05/2002

Completion date
27/05/2003

Eligibility

Key inclusion criteria
All adult patients admitted to the orthopaedic wards with an external fixator to the lower limb. Patients would have to have had a fresh procedure and should have had the external fixator applied during the current admission.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
27/05/2002

Date of final enrolment
27/05/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Orthopaedics
Bradford
United Kingdom
BD9 6RJ

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
Industry

Funder Name
Huntleigh Healthcare (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