ISRCTN07508485 https://doi.org/10.1186/ISRCTN07508485

Evaluation of vibro-pulse in the treatment of cellulitis of the lower limb

Submission date	Recruitment status
11/07/2006	No longer recruiting
Registration date	**Overall study status**
28/07/2006	Completed
Last Edited	**Condition category**
01/02/2010	Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
04/24

Study information

Scientific Title

Study objectives
To ascertain whether the application of cycloidal vibration (vibro-pulse) would reduce treatment time compared to current standard treatment alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Doncaster Local Research Ethics Committee and Medicines and Healthcare Products Regulatory Agency, dated: 13/03/04 (reference number: 04/24).

Study design
Non-blind 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

Health condition(s) or problem(s) studied
Lower limb cellulitis (erysipelas)

Interventions
Control group: prescribed antibiotics and bed rest.
Experimental group: prescribed antibiotics, bed rest and cycloidal vibration (vibro-pulse) three times a day for 30 minutes per treatment.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The daily amount of erythema/cellulitis and oedema reduction against time up to seven days.

Secondary outcome measures
Blood tests (white cell count [WCC])

Overall study start date
01/06/2004

Completion date
01/01/2006

Eligibility

Key inclusion criteria
1. Diagnosed cellulitis (erysipelas) of the lower limb
2. Prescribed treatment of either oral or intravenous antibiotics and bed rest

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Pregnancy
2. Under 18 years old
3. Diagnosed with deep vein thrombosis
4. Non-compliant with medical treatment

Date of first enrolment
01/06/2004

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Doncaster Royal Infirmary
Doncaster
United Kingdom
DN2 5LT

Sponsor information

Organisation
Doncaster and Bassetlaw NHS Foundation Trust (UK)

Sponsor details
Armthorpe Road
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Sponsor type
Hospital/treatment centre

Website
http://www.dbh.nhs.uk/

ROR
https://ror.org/01yc93g67

Funder(s)

Funder type
Industry

Funder Name
Vibrant Medical Ltd (UK)

Funder Name
Doncaster and Bassetlaw NHS Foundation 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	01/04/2007		Yes	No