

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

Submission date 11/07/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/07/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 01/02/2010	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data

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
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