ISRCTN21800909 https://doi.org/10.1186/ISRCTN21800909

The management of neuropathic ulcers of the foot in diabetes by shock wave therapy

Submission date	Recruitment status	[ ] Prospectively registered
02/07/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/09/2008	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

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
838/CE

Study information

Scientific Title

Acronym
SWDF

Study objectives
The main objective of the present study was to evaluate healing rates of diabetic foot ulcers during a 20-week period in patients treated by extracorporeal shock wave therapy (ESWT) compared with standard therapy consisting of debridement and Silver dressing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee (Comitato Etico Indipendente Locale Azienda Ospedaliera Ospedale Policlinico Consorziale di Bari) on the 24th June 2008 (ref: 838/CE).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Neuropathic Diabetic Foot Ulcers

Interventions
Shock waves and Silvercel dressing versus Silvercel dressing alone. Follow-up in all arms and treatments is for 20 weeks with standard dressing every 3 - 4 days.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

1. Wound area reductions, measured with the Rhinoceros program
2. Time to complete ulcer healing, measured as the number of days from the start of treatment to the date that a patient achieved complete wound healing. If the healing wasn't within the 20 weeks of the study, the patient was considered as non-healing and the time wasn't registered.
3. Time to complete healing
4. Index of re-epithelisation of the wound area

The outcomes were measured every 10 days.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/10/2006

Completion date
31/03/2007

Eligibility

Key inclusion criteria
1. A neuropathic foot plantar ulcer below the malleoli for a period of at least 15 to 30 days with an area wider than 1 cm^2
2. 30 - 70 years old, either sex
3. Diameter of the lesion between 0.5 to 5 cm
4. Diabetes mellitus type I; in insulin treatment since at least 5 years ago

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Peripheral vascular disease
2. By-pass
3. Pregnant
4. Coagulation diseases
5. History of neoplasia
6. Other conditions based on the principal investigator's clinical judgement around the ESWT applications

Date of first enrolment
01/10/2006

Date of final enrolment
31/03/2007

Locations

Countries of recruitment
Italy

Study participating centre
via Napoli, 215
Bari
Italy
70124

Sponsor information

Organisation
University of Bari (Italy)

Sponsor details
Piazza G. Cesare, 11
Bari
Italy
70124

Sponsor type
University/education

Website
http://www.uniba.it/

ROR
https://ror.org/027ynra39

Funder(s)

Funder type
University/education

Funder Name
University of Bari (Italy)

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