

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

Submission date

02/07/2008

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

29/09/2008

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

29/09/2008

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Biagio Moretti

Contact details

via Napoli, 215

Bari

Italy

70124

Additional identifiers

Protocol serial number

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).

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

No secondary outcome measures

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 cm²
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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/027ynra39>

Funder(s)

Funder type

University/education

Funder Name

University of Bari (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration