

# 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).

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**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 cm<sup>2</sup>
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