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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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

### Contact name

Prof Biagio Moretti

### Contact details

via Napoli, 215 Bari Italy 70124

### 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<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

### 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