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Effectiveness of extracorporeal shock wave therapy in patients with proximal plantar fasciitis

Submission date	Recruitment status	[ ] Prospectively registered
02/07/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/09/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/08/2014	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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ST833
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Changes of proximal plantar fascia microcirculation after extracorporeal shock wave therapy in patients with proximal fasciitis: a double blinded randomised controlled trial

Study objectives
1. There will be an increase in microcirculation at the proximal plantar fascia (PPF) in chronic plantar fasciitis patients
2. Short term and long term changes no microcirculation can be observed after application of extracorporeal shock wave therapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Hong Kong Polytechnic University, 18/06/2009, ref: HSEARS20090618004

Study design
Double-blinded randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic plantar fasciitis

Interventions
Patients will be randomised by drawing cards to receive 3 or 6 sessions of radial extracorporeal shock wave therapy (ESWT) treatment (Storz Medical, Duolith SD, Switzerland), or no active treatment (control). The outcome measures will be taken before, immediately after, at 3, 6 and 12 months after intervention.

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Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Microcirculation index, measured before, immediately after, at 3, 6 and 12 months after intervention

Key secondary outcome(s))

1. Plantar fascia thickness, measured before and 6 and 12 months after intervention
2. Ankle range of motion, measured before and 6 and 12 months after intervention
3. Foot Function Index, measured before, immediately after, at 3, 6 and 12 months after intervention
4. Visual Analogue Scale (VAS), measured before and 6 and 12 months after intervention

Completion date
01/09/2011

Eligibility

Key inclusion criteria
1. Aged between 18 and 60 years (either sex)
2. Suffered from proximal heel pain for more than 3 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Key exclusion criteria
1. Surgery in the treatment area
2. Peripheral vessel diseases
3. Diabetes mellitus
4. Peripheral neuropathy
5. Foot fracture
6. Ankle sensation loss

Date of first enrolment
01/09/2009

Date of final enrolment
01/09/2011

Locations

Countries of recruitment

China

Study participating centre
ST833
Hong Kong
China
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Sponsor information

Organisation
The Hong Kong Polytechnic University (China)

ROR
https://ror.org/0030zas98

Funder(s)

Funder type
University/education

Funder Name
The Hong Kong Polytechnic University (China) - Department of Rehabilitation Sciences

Results and Publications

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	01/10/2013		Yes	No