ISRCTN87901404 https://doi.org/10.1186/ISRCTN87901404

A "new" regimen for eccentric loading versus shock wave treatment for chronic insertional Achilles tendinopathy

Submission date	Recruitment status	[ ] Prospectively registered
13/05/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/06/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/06/2010	Musculoskeletal Diseases	[ ] 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
N/A

Study information

Scientific Title
Eccentric loading versus shock-wave therapy for insertional Achilles tendinopathy: a randomised controlled trial

Study objectives
A new regimen of eccentric calf muscle training provides equivalent outcome as shock-wave therapy (SWT) for recalcitrant insertional Achilles tendinopathy

Ethics approval required
Old ethics approval format

Ethics approval(s)
The local medical ethics committee (Ethik-Kommission, Landesärztekammer Rheinland-Pfalz) approved on the 13th of December 2005 (ref: 4988)

Study design
Randomised active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Insertional Achilles tendinopathy

Interventions
1. Eccentric Loading:
All patients were given a practical demonstration and hand written instructions of the exercises by the same physician at the beginning of the study. The eccentric calf muscle training was performed in an upright body position with a straight leg. The patients performed a heel raise with the non-injured leg, then all body weight was transferred to the injured side, and from the heel raised position the patients slowly lowered the heel to the floor-level. There was no load with the ankle in dorsiflexion. This was done 3 times for 15 repetitions, twice a day, 7 days/week, for 12 weeks. If there was no pain during the exercise the load was increased by using a backpack that was gradually filled with weights to reach a new level of painful training.

2. Shock-Wave Therapy:
Patients received SWT administered by the senior author. A radial shock wave device (EMS Swiss Dolorclast, Munich, Germany) was used. A projectile in a handpiece is accelerated by a pressurised air source and strikes a 15mm diameter metal applicator. The energy generated is transmitted to the patients skin as a shock wave through a standard commercially available ultrasound gel. The wave then disperses radially from the application site into the tissue to be treated. The energy generated depends considerably on the working pressure to which the device has been set. Following previous recommendation20, SWT was performed three times, spaced one week apart. At each of the three sessions, 2000 pulses were applied with a pressure of 2.5 bar (equalling an energy flux density of 0.12 mJ/mm²). The treatment frequency was 8 pulses/sec. Using the principle of clinical focusing, the area of maximal tenderness was treated in a circumferential pattern, starting at the point of maximum pain. No local anaesthetic was applied.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Victorian Institute of Sports Assessment Achilles (VISA-A) Score:
At each visit, every patient completed the VISA-a questionnaire which is validated for Achilles tendon problems. It contains eight questions that cover the three domains of pain (questions 1 - 3), function (questions 4 - 6), and activity (questions 7 and 8). Questions one to seven are scored on a basis of 10 points, and question 8 has a maximum of 30. Scores are summed to give a total. An asymptomatic person would score 100.

Secondary outcome measures
1. General outcome was scored by the patient on a six-point Likert scale ranging from 1 to 6. For the computation of success rates, patients who rated themselves 1 or 2 (i.e. completely recovered or much improved) were counted as successes.
2. Pain assessment
2.1. Patients also scored the severity of their main complaint, pain during the day, and inconvenience on an 11-point numerical rating scale (NRS; 0=no pain to 10=very severe pain).
2.2. An algometer (Pain Test-Model FPK, Wagner Instruments, Greenwich, CT) was used as a semi-objective measuring device that allows assessment of pressure pain threshold and tenderness using a 1 cm² tip.
2.3. Pain threshold was defined as the minimum pressure captured through its 1cm² tip which induced pain in the most tender area of the Achilles insertion.
2.4. Tenderness was defined as the pain rating on the numeric rating scale induced when a pressure of 3 kg was applied to the most tender area of the Achilles tendon insertion.

Outcomes will be measured at baseline, 2, 4 and 15 months.

Overall study start date
01/01/2008

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Adult patients with chronic recalcitrant (> 6 months) insertional Achilles tendinopathy
2. All patients had been treated unsuccessfully for at least 3 months, including local injections and non-steroidal anti-inflammatory drugs and physiotherapy

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Patients presenting with bilateral Achilles tendinopathy
2. Patients presenting with superficial or retrocalcaneal fluid on the ultrasound examination as a sign of bursitis
3. Patients showing a Haglunds deformity, a prominent postero-superior lateral aspect of the calcaneus, with a Fowler-Philip angle of greater than 75° on plain radiographs. All patients had plain radiographs of the calcaneus to identify tendon calcification.

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Germany

Study participating centre
OrthoTrauma Evaluation Center
Mainz
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Sponsor information

Organisation
OrthoTrauma Evaluation Centre (Germany)

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
OrthoTrauma Evaluation Centre (Germany) - Investigator initiated trial

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