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Arthroscopic surgery combined with postoperative shock wave therapy for treating osteochondral lesions of the talus

Submission date
01/02/2017

Recruitment status
No longer recruiting

Registration date
03/02/2017

Overall study status
Completed

Last Edited
02/02/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
An osteochondral lesion of the talus (OLT) is a common condition involving injuries to the talus (the bottom bone of the ankle joint) that involve both the bone and the overlying cartilage. These injuries are usually caused by a single traumatic injury to the ankle joint, such as a sprain, and symptoms include pain, swelling and instability of the joint. This can leads to problems putting weight on the ankle, causing problems with mobility. Treatment of OLT may involve non-surgical techniques such as wearing an ankle brace or surgery to restore the normal shape and movement of the talus. For patients with Hepple Phase I-III OLT (where the fracture has not separated the bone fragments) surgery is usually performed using arthroscopic techniques (which use a camera and small instruments to view and work within the joint through small incisions). This is generally effective however some patients still suffer from long-term pain after surgery. Shock wave therapy (SWT) is a type of physical therapy which uses sound waves to stimulate healing. The aim of this study is to find out whether treatment with SWT can help reduce pain and improve healing after arthroscopic surgery for OLT.

Who can participate?
Adults with OLT who are admitted to one of the four participating hospitals.

What does the study involve?
Participants who have received standard arthroscopic surgery are randomly allocated to one of two groups 10-12 weeks after surgery. Those in the first group have shock wave therapy. This involves applying low levels of sound waves to the affected area every other day for five treatments and gradually increasing the amount of energy used. Those in the second group are treated using equipment similar with the shock wave treatment in appearance but that does not produce any sound waves (dummy treatment). At the start of the study and then after six weeks, three, six and twelve months, participants in both groups are asked to rate their pain levels and ankle function. In addition, the ankle joint is scanned to evaluate healing three and twelve months after surgery.

What are the possible benefits and risks of participating?
Participants benefit from receiving high level OLT assessments. As the effectiveness of the combined treatment is not yet proven, the opportunity to receive this shock wave treatment cannot be called a benefit. There is a small risk of skin irritation or redness from the shock treatment and a very small risk of injury to the nerves or bones from having the treatment.

Where is the study run from?
1. Southwest Hospital (China)
2. Chinese People's Armed Police General Hospital (China)
3. Beijing Tongren Hospital (China)
4. Huashan Hospital (China)

When is the study starting and how long is it expected to run for?
December 2016 to July 2019

Who is funding the study?
Southwest Hospital (China)

Who is the main contact?
Professor Xiaojun Duan
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V1.3

Study information

Scientific Title
Arthroscopicsurgery combined with postoperative shock wave therapy for treating osteochondral lesions of the talus: A prospective, multicentre, randomised, double-blind clinical study

Study objectives
The aim of this study is to estimate the safety and feasibility of arthroscopic surgery combined with postoperative shock wave therapy for treating osteochondral lesions of the talus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Board: Medical Ethics Committee of Southwest Hospital, China, 24/01/2017, ref: [2017] No. 8 Keyan

Study design
Prospective double-blind multi-centre randomised controlled 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Osteochondral Lesions of the Talus, Hepple Phase -

Interventions
Patients who are diagnosed as Osteochondral Lesions of the Talus (OLT) at the outpatient department will be admitted to the hospital. The OLT will be treated with conventional

arthroscopic surgery and micro-fracture. 10-12 weeks after operation, if no complications are found, the patients will be selected as the participants of the study after obtaining their consents. The participants will be randomly allocated to one of two groups.

Experimental group: Participants will be treated with shock wave treatment at 12 weeks post-operatively. The energy level of the shock wave treatment should be adjusted according to the pain sensitivity of each participant, starting from low-level and gradually increasing to the required level; the energy density will be set at 0.18-0.25mJ / mm2. 2-3 treatment points will be chosen in each treatment; each point will receive shock wave for 1000 times, totaling 2000-3000 times. The treatment will be given on every other day. 1 course consists of 5 treatments, and the participants in the experimental group will be treated for 1 course.

Control group: Participants will be treated by equipment similar with the shock wave treatment in appearance but has no energy output.

Participants are followed up by the visual analogue scale (VAS) and AOFAS scoring system at baseline, 6 weeks, 3, 6 and 12 months; as well as MRI imaging at pre-operatively, and 3, 12 months post-operatively.

Intervention Type
Mixed

Primary outcome measure
1. Function of the ankle joint is measured using the AOFAS scoring system at baseline, 6 weeks, 3, 6 and 12 months
2. Pain in the ankle joint is measured using the visual analogue scale at baseline, 6 weeks, 3, 6 and 12 months
3. Repair of the OLT is assessed using MRI scanning pre-operatively, and 3 and 12 months post-operatively

Secondary outcome measures
1. Patient death rate is assessed by reviewing medical notes at 12 months
2. Serious complications that require other treatment are assessed by participant interviews at 12 months

Overall study start date
05/12/2016

Completion date
31/07/2019

Eligibility

Key inclusion criteria
1. Age 18 years or more and less than 80 years (including 80 years)
2. The disease lasts for more than 6 months; symptoms still remain after drug treatment
3. MRI suggests the diagnosis of Hepple Phase- Osteochondral Lesions of the Talus
4. The AOFAS score is lower than 75 after 10-12 weeks of ankle arthroscopy
5. Patients who sign the informed consent, agree to participant in the study and cooperate during the follow-up

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
32

Key exclusion criteria
1. Age less than 18 years or more than 80 years
2. MRI suggests Hepple Phase Osteochondral Lesions of the Talus associated with huge bone cyst
3. X-ray suggests malalignment of the lower limb or ankle joint (varus, valgus> 10 degrees)
4. Surgery history and shock wave treatment history of the ankle joint
5. Ankle OA, gout, local infection, coagulation abnormalities
6. Ankle ligamentous injury, or associated with other lesions that need surgical intervention
7. Pregnant women, deaf patients, or patients with mental disorders, etc., are excluded to ensure the accuracy of the follow-up
8. AOFAS scores of 10-12 weeks after ankle arthroscopy more than or equal to 75

Date of first enrolment
01/02/2017

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
China

Study participating centre
Southwest Hospital
No. 30 Gaotanyan Street
Shapingba District
Chongqing
China
400038

Study participating centre
Chinese People’s Armed Police General Hospital
No. 69, Yongding Road
Haidian District
Beijing
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100039

Study participating centre
Beijing Tongren Hospital
No. 1 Dongjiaominxiang
Dongcheng District
Beijing
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100730

Study participating centre
Huashan Hospital
No. 12 Urumqi Middle Road
Shanghai
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200040

Sponsor information

Organisation
Southwest Hospital

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Sponsor type
Hospital/treatment centre

ROR

https://ror.org/02jn36537

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Southwest Hospital

Results and Publications

Publication and dissemination plan
The study will be reported at the 22nd International Society for Medical Shockwave Treatment (ISMSC) Congress held in 2019. Planned publication in a high-impact peer reviewed journal in 2020.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date