ISRCTN74606904 https://doi.org/10.1186/ISRCTN74606904

Dosage effects of extracorporeal shockwave therapy in early hip necrosis

Submission date	Recruitment status	[ ] Prospectively registered
29/04/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/05/2016	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/09/2020	Musculoskeletal Diseases	

Plain English summary of protocol
Background and study aims
Osteonecrosis is a disease caused by reduced blood flow to the bones in the joints. The bone starts to die and may break down. Osteonecrosis can affect the femoral head, which is the highest part of the thigh bone that “plugs into” the hip socket. Extracorporeal shockwave therapy (ESWT) is a procedure where a device passes sound waves through the skin to the affected bone, improving the blood flow. This study investigates the effects of different doses of ESWT on patients with early osteonecrosis of the femoral head (ONFH).

Who can participate?
Patients aged over 18 with ONFH

What does the study involve?
Participants are randomly allocated into three groups which receive different doses of ESWT. Participants are assessed with x-ray and MRI scans, and blood samples are taken.

What are the possible benefits and risks of participating?
ESWT may relieve pain and improve hip function.

Where is the study run from?
Kaohsiung Chang Gung Memorial Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
August 2011 to July 2015

Who is funding the study?
Chang Gung Medical Foundation (Taiwan)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
98-2554A3

Study information

Scientific Title
Extracorporeal shockwave technology in hip necrosis: a dosage validation and systemic concentrations of serum NO levels of angiogenesis and osteogenesis factors and other biomarkers

Study objectives
The etiology of osteonecrosis of the femoral head (ONFH) is multi-factorial, and the treatment is disease stage dependent. Core decompression with or without bone grafting for symptomatic early stage ONFH, and total hip replacement for late stage of the disease are considered the gold standards. However, the results of core decompression are inconsistent and unpredictable despite of good results reported in selective series, and many patients eventually undergo hip replacement surgery. Therefore, an effective non-invasive method of treatment is imperative and attractive for patients with early ONFH.

This study investigated the systemic and local effects of different dosages of extracorporeal shockwave therapy (ESWT) in early osteonecrosis of the femoral head (ONFH).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Institutional Review Board of Chang Gung Memorial Hospital, 25/03/2010, IRB no: 98-2554A3

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteonecrosis of the femoral head

Interventions
The initial protocol intends to recruit 60 patients. Patients are randomly divided into three groups with 20 patients in group I who receive 2000 impulses of ESWT at 24 Kv; 20 patients in group II who receive 4000 impulses of ESWT at 24 Kv and 20 patients in group III who receive 6000 impulses of ESWT at 24 Kv.

Intervention Type
Device

Primary outcome(s)
1. The number of total hip arthroplasty (THA) performed during the study period (1 year)
2. Pain (VAS) score and Harris hip score
3. Changes on X-ray and MRI studies

Key secondary outcome(s))
Ten milliliters of peripheral blood are obtained for measurements of serum NO level, VEGF and TGF-α; BMP-2, osteocalcin, DKK-1, IGF and IL-6 before treatment and at 1, 3, 6 and 12 months after treatment.

Completion date
31/07/2015

Eligibility

Key inclusion criteria
1. Over 18 years old
2. ONFH in stage I, stage II or stage III-a according to ARCO classification at initial presentation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Total final enrolment
33

Key exclusion criteria
1. Patients with late stages of the disease (stages III-b, III-c or stage IV)
2. Patients under 18 years of age
3. Patients with cardiac arrhythmia or pacemaker
4. Patients on immunosuppressant drugs
5. Patients with infection or advanced arthritis
6. Patients with coagulopathy
7. Chronic renal failure
8. Pregnancy
9. Poor compliant patients

Date of first enrolment
24/10/2011

Date of final enrolment
24/07/2015

Locations

Countries of recruitment
Taiwan

Study participating centre
Kaohsiung Chang Gung Memorial Hospital
123, Ta Pei Road
Niao Sung District
Kaohsiung
Taiwan
83305

Sponsor information

Organisation
Chang Gung Medical Foundation (Taiwan)

ROR
https://ror.org/02verss31

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chang Gung Medical Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Taiwan

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2016	02/09/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes