Treatment of osteoporosis with unfocused extracorporeal shock wave therapy: pilot study

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A clinical pilot-study were we will look if one time shock wave therapy on the distal radius leads to an increased bone mass. At the same time we would like to study if shock wave therapy of the distal radius could result in complications and we...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON41686

Source
ToetsingOnline

Brief title
Shock wave therapy for osteoporosis

Condition

- Bone disorders (excl congenital and fractures)

Synonym
osteoporosis, porous bones

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Annafonds

Intervention

Keyword: Osteoporosis, Unfocused extracorporeal shock wave therapy

Outcome measures

Primary outcome

The objective of the present study is to examine whether a single treatment

with unfocused extracorporeal shock wave therapy to the distal forearm leads to

an increased bone mass.

Secondary outcome

To provide novel data which can be used to generate power analysis for clinical

follow-up studies.

To assess whether UESWT results in pain and/or complications.

Study description

Background summary

Osteoporotic fractures have a high morbidity and mortality. This is why prevention of these fractures is important. Today's standard treatment is lifestyle modifications in combination with bisphosphonates, which results in prevention of further bone loss. We have shown in animal studies that one-time treatment with unfocused extracorporeal shock wave therapy (UESWT) leads to bone formation. This could be an interesting clinical implication for the prevention of osteoporotic fractures.

Study objective

A clinical pilot-study were we will look if one time shock wave therapy on the distal radius leads to an increased bone mass. At the same time we would like to study if shock wave therapy of the distal radius could result in complications and we would like to generate new data which is essential for large scale studies.

Study design

Female patients who are on the operation list waiting for a procedure on the lower extremity or spine under general anaesthesia at the department of orthopaedics of the UMC Utrecht in the age of 50 and 80 years, will be contacted about the study by the researcher. We will inform the patient about the study and invite them to participate. If they are interested the researcher will screen on inclusion and exclusion criteria and schedule an appointment before or after one of the patients other appointments in our hospital before the operation (eg. anaesthesiologist or a nurse practisioner). The appointments will be centred at study office hours. The patient will receive written information and a questionnaire by mail. At the appointment the patient will be further screened on in-and exclusion criteria, also with the questionnaire.
When the patient fulfils the inclusion criteria and gives written informed consent, the baseline measurements will be carried out. Thereafter the patient will be randomized in either left or right limb treatment and X-ray exams and DXA-scans are made. The attending physician will be informed about the treatment allocation. During the operation on the lower extremity patient is treated with 3000 extracorporeal shock waves with an EFD of 0.3 mJ/mm2 at one wrist. This will be done in a single blind manner, so that the subject does not know which site has been treated. The effect of one-time unfocused extracorporeal shock wave therapy will be measured in different ways. First, we will make a dual energy X-ray absorptiometry (DXA)-scan of the treated and control site at six and twelve weeks after unfocused extracorporeal shock waves to examine bone mineral density of the distal forearm to follow the effect in time. The pain at the wrist will be objectified before the operation and during the first week with a diary (three times daily). We will perform clinical and physical examination of the wrists at the clinical department of orthopaedics the day after the operation or before they leave the hospital if they leave the hospital the day of the operation. After UESWT an X-ray is only made on indication. In total we will treat 12 patients.

Intervention

Patients will recieve 3000 unfocused shock waves with an energy flux density of 0.30,3mJ/mm2 to one of both wrists.

Study burden and risks

Unfocused shock wave therapy (UESWT) is a non-invasive therapeutic modality without surgery or surgical risks. It has only been used in other areas like wound healing, without any complications described so far. There are positive effects of UESWT in wound healing, where UESWT-treated ulcers showed significant improvement in blood flow perfusion rate. UESWT also showed increases in cell proliferation and decreases in cell apoptosis. Safe use of ESWT has even expanded to cardiovascular medicine.
The use of ESWT steadily increases over the years. The only side effects of ESWT are local reddening, ecchymosis, or mild hematoma, which have a low rate

and are easily conservativly managed with success.
With lithotripsy (kidney stone disintegration), which uses focused shock waves, the rarely described side effects are hematomas, deep vein thrombosis, fat embolism, and pulmonary embolism or neurovascular complication. Because this treatment is of a complete different modality and at a different region of the body, we do not expect to see any of these side effects.
As said, shock wave therapy has emerged as a good and safe choice in the treatment of many orthopaedic disorders.

The burden for the patient is low, because the pain is controlled during the treatment because of the general anesthesia and afterwards with pain medication according to the standard post-operative protocols used in the UMC Utrecht, but ofcourse depending on the type of lower extremity surgery that is performed.
The measurements (DXA-scan en X-rays) have very low radiation risks and the appointments are scheduled together with the pre- and post-operative planned appointments, so the patients do not have to come more times then necessary to the hospital.

This pilot study is a kind of 'proof of principle', but it is definately performed with clear vision of clinical implications for the prevention of all osteoporotic bone fractures.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Female patients, age 50-80 years, normal dietary intake inclusive calcium and/or milk products and willing to participate

Exclusion criteria

Skin disease, systemic corticosteroid use, known with systemic disease that interacts with bone (eg. multiple myeloma, hyper(para)thyroidism, Paget*s disease or Cushing*s disease) or a previous wrist fracture

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-05-2015
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	Extracorporeal shock wave therapy
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-02-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-04-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-03-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL40580.078.12