Treating non-healing atypical femur fractures (AFF) with extracorporeal shock wave therapy (ESWT); a pilot-study.

Published: 30-10-2019
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The primary research question includes: Can ESWT induce fracture healing in non-healing AFF's after six months?

Ethical review	Approved WMO
Status	Pending
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON48267

Source
ToetsingOnline

Brief title
ESWT for non-healing AFF

Condition

- Fractures

Synonym
atypical femur fracture; spontaneous fracture of the upper leg

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: atypical femur fracture, bisphosphonate, shock wave therapy

Outcome measures

Primary outcome

Number of healed AFF's after six months assessed with CT-scan.

Secondary outcome

Number of healed AFF's after 3 monts, changes in patient reported outcome

measures at 3 and 6 month compared to baseline.

Study description

Background summary

Patients with atypical femur fractures are usually treated surgically with an intramedullary nail. However, due to poor bone quality, AFF's often experience problems with consolidation.A non-healing AFF is a highly disabling condition for which no effective treatment does exist. Application of extracorporeal shock wave therapy (ESWT) is a very potent non-invasive therapy for bone regeneration because is stimulates early angiogenesis and subsequent osetogenesis. ESWT is an effective treatment in non-healing fractures and could therefore be an effective treatment for non-healing AFF's as well.

Study objective

The primary research question includes: Can ESWT induce fracture healing in non-healing AFF's after six months?

Study design

Pilot-study

Intervention

Patients participating in the study will be treated with ESWT twice, at a two week interval. Patients will be treated at our day care facility under local or general anesthesia. During one treatment of ESWT 4000 shocks will be applied at

an energy density level of 0.59 mJ/mm2, which will take about 30 minutes.

Study burden and risks

ESWT is used worldwide for treatment of orthopedic disorders, including treatment of non-healing fractures. In the current study the same treatment protocol is used as in treatment for non-unions of long bones. Besides local reddening and ecchymosis no other side effects have been found.

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

- AFF according to the American Society for Bone and Mineral Research Task

Force created guidelines
- Time since primary surgical fixation of the AFF more than > 1 year
- Fracture gap <5 mm
- Good understanding of the Dutch language and willing to participate
- 18 years or older

Exclusion criteria

- Instable or displaced AFF
- Active infection
- Haemophilia

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2019
Enrollment:	10
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO

Date:	30-10-2019

Application type:	First submission
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	NL69232.078.19