Assessment of fracture healing by high-resolution peripheral quantitative computer tomography (HRpQCT) and bone strength analysis in standard care and after immediate administration of vitamin D.

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Fracture healing groupPrimary outcome: to study the healing of distal radius fractures in terms of calculated bone strength based on the results of cortical and trabecular bone parameters using a novel HRpQCT technique (XtremeCT device, Scanco,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone, calcium, magnesium and phosphorus metabolism disorders
Study type	Interventional

Summary

ID

NL-OMON41626

Source
ToetsingOnline

Brief title
Fracture healing by HRpQCT in standard care and after vitamin D.

Condition

- Bone, calcium, magnesium and phosphorus metabolism disorders
- Fractures

Synonym
distal radius fracture, wrist fracture

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: fracture healing, HRpQCT, vitamin D, XtremeCT

Outcome measures

Primary outcome

Fracture healing group:

The primary objective is to study healing of distal radius fractures in postmenopausal women in terms of alterations in micro-architecture and calculated bone strength based on the results of cortical and trabecular bone parameters in the first 12 weeks after fracture, using a novel high resolution peripheral quantitative computer tomography (HRpQCT) device. Using this technique we will develop a computer based model for fracture healing

Intervention group:

Primary outcome: to compare the effect of immediate administration of two dosages of vitamin D (800 and 2000 IU/day) vs. standard care (administration of vitamin D more than 12 weeks after fracture) on fracture healing and functional outcome.

Secondary outcome

Intervention group:

Secondary outcome: to compare the healing of distal radius fractures in terms

of calculated bone strength based on the results of cortical and trabecular bone parameters using HRpQCT (XtremeCT device, Scanco, Switzerland) using the developed computer based model, between immediate vitamin D supplementation (800 and 2000 IU/day) and standard care.

Study description

Background summary

Fractures of the distal radius are one of the most frequent trauma fractures. The incidence is roughly 17 percent of all fractures. Although sometimes stated otherwise, the outcome of the distal radius fractures is not uniformly good regardless the treatment instituted. The cause of the poor outcome has been related to poor restoration of anatomy and secondary loss of reduction after initial adequate reduction. Both surgical and conservative treatment of the distal radius fractures can be challenging since they might be associated with complications including stiffness, loss of reduction, malunion, instability, loss of radial length, infection, tendon rupture, sensory neuritis, and carpal tunnel syndrome.

In regular daily practice, fracture healing is evaluated by clinical judgment of the physician in combination with the results of conventional X-ray. However, these evaluations do not provide detailed information with regard to the healing process and consolidation of fractures on the level of cortical and trabecular bone micro-structure. Until recently, the structural properties of bone could only be studied in-vitro because of the lack of measurement techniques and / or technical or radiation issues in-vivo. Thanks to the development of new low radiation HRpQCT techniques (such as the XtremeCT device) these micro-structural aspects of bone can be studied in patients. We showed that the fracture healing process can be studied and modeled in detail using this new technique and we demonstrated that early changes in bone parameters measured by HR-pQCT predicted the clinical outcome at 12 weeks post-fracture. This type of research can provide new insights regarding to the fracture healing process in vivo and probably attribute to the understanding of non-union of fractures and non-optimal functional outcomes as well as the possible (positive or negative) influence of different types of medication on (delayed or enhanced) fracture healing. It has been demonstrated that there is a positive influence of vitamin D3 and calcium supplementation over the first 12 weeks after fracture. Whether this results in more stable fractures, or applies to other osteogenic bone agents such as bisphosphonates and other medications available remains to be examined.

We therefore propose this study in order to examine the ability to evaluate fracture healing and to develop a fracture healing computer model based on HRpQCT measurements of distal radius fractures in post-menopausal women with and without vitamin D supplementation, with and without calcium supplementation and with and without calcium + vitamin D supplementation.

Study objective

Fracture healing group
Primary outcome: to study the healing of distal radius fractures in terms of calculated bone strength based on the results of cortical and trabecular bone parameters using a novel HRpQCT technique (XtremeCT device, Scanco, Switzerland) and to develop a computer based model for fracture healing.

Intervention group
Primary outcome: to compare the effect of immediate administration of two dosages of vitamin D (800 and 2000 IU/day) vs. standard care (administration of vitamin D more than 6 weeks after fracture) on fracture healing and functional outcome.
Secondary outcome: to compare the healing of distal radius fractures between immediate vitamin D supplementation (800 and 2000 IU/day) and standard care in terms of calculated bone strength based on the results of cortical and trabecular bone parameters using HRpQCT (XtremeCT device, Scanco, Switzerland) and the developed computer based model.

Study design

A single centre consecutive, prospective cohort of 16 postmenopausal women with a stable distal radius fracture for the evaluation of healing of distal radius fractures and implementation of a computer based model for fracture healing using a HRpQCT technique.
An intervention study with 30 postmenopausal women with a stable distal radius fracture to compare the effect of immediate administration of vitamin D on fracture healing with usual care (i.e. administration of vitamin D: 12 weeks or more after fracture). Enrolled subjects who have been removed of the study will be replaced.

Intervention

30 postmenopausal women with a non-operative stable distal radius fracture to compare the effect of immediate administration of vitamin D on fracture healing with usual care (i.e. administration of vitamin D: 12 weeks or more after fracture).

Study burden and risks

Based on the results of literature study (see page 10 protocol) our study proposal with vitamin D doses of 800 or 2000 IU/d is save with regard to possible toxicity. The radiation dose of the measurements with Xtreme CT is 72 microSv, which is less than a flight to San Fransisco or a conventional CT scan.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1.Postmenopausal women older than 50 years who present themselves in clinic with a distal radius fracture due to a trauma. 2.2. Patients with any non-operative stable distal radius fracture that is treated by cast immobilization. 3.Patients who understand the conditions of the study and are willing and able to comply with the scheduled biochemical and radiographic evaluations. 4.Patients who signed the Ethics Committee approved specific

Informed Consent Form prior to inclusion.

Exclusion criteria

1.Patients who underwent surgery of the wrist or radius on a previous occasion on the same side or who need surgery this time. 2.Patients with active or suspected infection such as pneumonia or complicated urinary tract infection in the last 3 months. 3.Patients with malignancy in the last 12 months. 4.The patient with a neuromuscular or neurosensory deficit which would limit the ability to assess the performance during the healing period. 5.Patients with known systemic or metabolic disorders leading to progressive bone deterioration: hyperthyroidism, hyperparathyroidism, chronic kidney disease with eGFR<30 ml/min 6.Patients with an active inflammatory disease during the last year such as reumatoid arthritis, SLE, inflammatory bowel disease (M. Crohn and colitis ulcerosa) 7.The prolonged use of oral glucocorticoids during the last 6 months 8.Patients, who as judged by the principal Investigator, are mentally incompetent or are unlikely to be compliant with the follow-up evaluation schedule. 9.Patients with other severe concurrent joint involvements which can affect their outcome. 10.Patients who are already selected for another trial concerning distal radius fractures.

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-10-2011
Enrollment:	52
Type:	Actual

Ethics review

Approved WMO Date:	06-04-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-01-2013
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	07-08-2013
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	29-01-2014
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	05-06-2014
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	24-06-2015
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21702
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL33512.068.10
OMON	NL-OMON21702