Assessment of fracture healing by high-resolution peripheral quantitative computed tomography (HR-pQCT) and bone strength analysis in standard care and after immediate administration of calcium supplementation

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

Summary

ID

NL-OMON41489

Source
ToetsingOnline

Brief title
Fracture healing assessed by HRpQCT in standard care and after calcium

Condition

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

Synonym
distal radius fracture, wrist fracture

Research involving
Human

Sponsors and support

Primary sponsor: Viecuri Medisch Centrum voor Noord-Limburg
Source(s) of monetary or material Support: Stichting De Wijerhorst

Intervention

Keyword: Calcium, Fracture healing, HRpQCT, Vitamin D

Outcome measures

Primary outcome

The main study parameters are the changes in cortical and trabecular bone parameters that will be assessed by HR-pQCT and the changes in estimated bone strength and stiffness as calculated in the µFEA.

Secondary outcome

The secondary study parameters are the standard clinical and functional outcomes that are obtained using the PRWE and QuickDASH questionnaires, the pain score using VAS and the range of motion assessment. Furthermore, blood serum markers for bone formation and resorption will be measured.

Study description

Background summary

In contrast to conventional X-ray, the cortical and trabecular changes in the healing bone can be studied in vivo at the micro scale using a recently developed low-dose HR-pQCT technique. Using this HR-pQCT technique we can gain new insights regarding the influence of different types of medication on (delayed or enhanced) fracture healing.

Study objective

The main objective is to compare the effect of immediate (or pre-existent) administration of daily calcium supplementation (1 Cacit bruisgranulaat *1000*: 1000 mg calcium) or two daily dosages of calcium + vitamin D (CaD® sachet 1000/880: 1000 mg calcium + 880 IU vitamin D; and 2 CaD® sachets 500/880: 1000 mg calcium + 1760 IU vitamin D) to standard care (administration of vitamin D3 12 weeks after fracture) in terms of calculated bone strength based on analysis of cortical and trabecular bone parameters using HR-pQCT (XtremeCT by Scanco, Switzerland).
The secondary objective is to compare the effect of immediate (or pre-existent) administration of daily calcium supplementation (1 Cacit bruisgranulaat *1000*: 1000 mg calcium) or two daily dosages of calcium + vitamin D (CaD® sachet 1000/880: 1000 mg calcium + 880 IU vitamin D; and 2 CaD® sachets 500/880: 1000 mg calcium + 1760 IU vitamin D) to standard care (administration of vitamin D3 12 weeks after fracture) on fracture healing and functional outcome.

Study design

A single-blind randomized controlled trial in 100 postmenopausal women allocated to five groups of equal group size. In a follow-up period of 1 year 6 visits are planned; visit 1 at 1-2 weeks after fracture; visit 2 at 3-4 weeks after fracture; visit 3 at 6-8 weeks after fracture; visit 4 at 12 weeks after fracture, visit 5 at 24 weeks post-fracture and visit 6 1 year after fracture.

Intervention

Group I receives standard care, i.e. start of administration of vitamin D3 12 weeks after fracture (control). Group II receives immediate administration of daily calcium supplementation (1 Cacit bruisgranulaat *1000*: 1000 mg calcium). Group III receives immediate administration of daily calcium + low dose vitamin D supplementation (1 CaD® sachet 1000/880: 1000 mg calcium + 880 IU vitamin D). Group IV receives immediate administration of daily calcium + high dose vitamin D supplementation (2 CaD® sachets 500/880: 1000 mg calcium + 1760 IU vitamin D). Group V already uses calcium and/or vitamin D supplementation. Their dose will be adjusted to the standard dose in accordance with the Dutch guidelines (1 CaD® sachet 5000/880: 500 mg calcium + 880 IU vitamin D).

Study burden and risks

Patients will be assessed during six visits spanning a total period of 1 year. Each visit takes approximately 55 minutes, so the total study time per subject will be 330 minutes. All visits, except the fifth and sixth visit, will be combined with the regular care visits.
During the study there will be 3 general physical examinations, 6 blood collections, each 20ml (total amount 120 ml, for bone markers and chemistry) and 10 HR-pQCT measurements with a total radiation dose of 100 µSv (10 times

10 µSv).

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

1. Postmenopausal women older than 50 years who present themselves in clinic with a distal radius fracture due to a trauma.
2. Patients with a stable distal radius fracture type 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 and the prescribed rehabilitation.
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 or a pathological fracture in the last 12 months.
4. Patients with a neuromuscular or neurosensory deficit, e.g. Parkinson*s disease, 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, such as: hyperthyroidism, hyperparathyroidism, chronic kidney disease with eGFR<30 ml/min, sarcoidosis, hypercalcemia
6. Patients with an active inflammatory disease during the last year such as rheumatoid arthritis, systemic lupus erythematous, inflammatory bowel disease, e.g. Crohn*s disease and ulcerative colitis.
7. The use of glucocorticoids during the last 12 months.
8. Patients with an allergy to calcium, calcium carbonate, cholecalciferol, aspartame, citric-acid, lactose, dimethicone, methylcellulose, sorbic acid, macrogole, polyvidone, mannitol, orange flavour, natriumsaccharine, starch or sucrose.
9. Patients, who as judged by the principal Investigator, are mentally incompetent or are unlikely to be compliant with the follow-up evaluation schedule.
10. Patients with other severe concurrent joint involvements that can affect their outcome.
11. 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:	Recruitment stopped
Start date (anticipated):	28-11-2014
Enrollment:	100

Type:	Actual

Ethics review

Approved WMO Date:	17-12-2013
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	31-03-2015
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	NL46035.072.13

Study results

Date completed:	18-06-2020
Actual enrolment:	40

Summary results

Trial is onging in other countries