# Fracture healing study.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON21702

**Source**
Nationaal Trial Register

**Health condition**

Fracture healing of distal radius fractures

### Sponsors and support

**Primary sponsor:** J.P.W. Van den Bergh
**Source(s) of monetary or material Support:** Stichting de Weijerhorst

### Intervention

### Outcome measures

**Primary outcome**

1. Study the healing of distal radius fractures in terms of calculated bone strength based on the results of cortical and trabecular bone parameters using HR-pQCT and to develop a computer based model for fracture healing;

2. Compare the effect of immediate administration of two dosages of vitamin D3 vs. standard care on fracture healing in terms of functional outcome.

**Secondary outcome**

Use the model to compare the effect of immediate administration of two dosages of vitamin

D3 vs. standard care on fracture healing in terms of bone strength.

# Study description

### Background summary

N/A

### Study objective

N/A

### Study design

Seven visits scheduled at 1-2 (baseline), 3-4, 6-8 and 12 weeks and 6, 12 and 24 months post-fracture.

### Intervention

Group 1: Standard care (administration of vitamin D3 12 weeks after fracture);

Group 2: Immidiate administration of vitamin D3 (800 IU/day) 1-2 and 6-8 weeks after fracture;

Group 3: Immidiate administration of vitamin D3 (2000 IU/day) 1-2 and 6-8 weeks after fracture.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Postmenopausal women older than 50 years with a stable distal radius fracture that is treated by immobilization with a cast;

2. Patients who understand the conditions of the study and are willing and able to comply with the scheduled evaluations and rehabilitation;

3. Patients who signed the informed consent form prior to inclusion.

## Exclusion criteria

1. Patients with a history of surgery of the wrist or radius at the fractured side or who need surgery this time;

2. Patients with an active or suspected infection in the last 3 months prior to the fracture;

3. Patients with malignancy in the last 12 months;

4. Patients 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, such as: hyperthyroidism; hyperparathyroidism; chronic kidney disease with eGFR<30 ml/min; sarcoidosis; hypercalcemia;

6. Patients with an active inflammatory disease during the last 12 months, such as: reumatiod arthritis; systemic lupus erythematosus; inflammatory bowel disease;

7. The use of glucocorticoids during the last 12 months;

8. Patients who, as judged by the prinicipal investigator, are mentally incompetent or are unlikely to be compliant with the follow-up evaluation schedule.

# Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-10-2011 |
| Enrollment: | 46 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 28-01-2013 |
| Application type: | First submission |

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 41626
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL3633 |
| NTR-old | NTR3821 |
| CCMO | NL33512.068.10 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |
| OMON | NL-OMON41626 |

# Study results

**Summary results**
N/A