# Dynamic bracing for OVCFs

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In patients suffering from an OVCF dynamic bracing will improve quality of life with a positive effect on pain and sagittal spinal alignment. Dynamic bracing improves gait quality and balance, as well as physical activity, and decreases the...

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| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON24180

**Bron**
Nationaal Trial Register

**Verkorte titel**
Dynamic bracing for OVCFs

**Aandoening**

Osteoporotic vertebral compression fractures (OVCFs)

### Ondersteuning

**Primaire sponsor:** Bauerfeind
**Overige ondersteuning:** ZonMw

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

The primary outcome parameter is quality of life at one year after intervention. This will be measured using the Quality of Life Questionnaire of the European Foundation for Osteoporosis (Qualeffo-41).

# Toelichting onderzoek

### Achtergrond van het onderzoek

OVCFs are the most common fractures among the elderly causing pain and long term morbidity. After an incident OVCF there is a 20% risk of an additional fracture in the next year. After a fracture, the disproportionate height loss from the anterior vertebral body results in wedging. Wedge accumulation over multiple thoracolumbar levels may lead to subsequent spinal deformity (vertebral fracture cascade). Spinal deformity has a profound impact on health, such as physical and pulmonary function, pain and disability, postural control, and mortality. Treatment of OVCFs should aim to break the downward spiral of recurrent fractures and to prevent the subsequent progression of global sagittal malalignment. Furthermore, it should intend to prevent or slow down the decline in postural control, thereby limiting the increased risk of falling in these frail patients.

Treatment generally includes a mix of analgesics, preventive osteoporosis medication and physical therapy (Richtlijn Osteoporose en Fractuurpreventie). However, for many patients current conservative treatment fails to provide adequate relief of pain and disability, nor does it prevent subsequent spinal deformity to end the vicious cycle of the vertebral fracture cascade.

Prevention of an increased anterior bending moment on the trunk is of high clinical importance to minimize overload on the anterior part of the spine (vertebral bodies) and thus to prevent new vertebral fractures. As was shown in our pilot study, six weeks of continuous bracing resulted in a more upright posture (i.e. decrease in anterior bending moment). This is clinically relevant since even a small increase in thoracic kyphosis results in a significant rise in vertebral compressive loading, and in an earlier study we found that a greater kyphosis angle is independently associated with increased risk of incident OVCFs.

We therefore hypothesize that dynamic bracing improves sagittal alignment and thereby decreases the risk of novel vertebral fractures. Currently, the use of conventional, rigid spinal orthoses is extremely limited in patients suffering from osteoporosis due to the suspected subsequent atrophy of the trunk muscles and restricted respiration leading to low patient compliance. The dynamic orthosis has been developed as an alternative to the standard three-point orthosis, aiming to overcome the disadvantages of a rigid brace. It shares the same biomechanical principle of the rigid three-point support, however with a less rigid immobilization and a dynamic behaviour allowing biofeedback activation of the dorsal lumbar musculature. In a comparative study, patients with a dynamic orthosis had more reduction in pain and a greater improvement in quality of life and respiratory function, with equal effectiveness in stabilizing the fracture, and fewer complications (39% versus 12%).

Since OVCFs are an increasing health problem with serious clinical consequences, high-quality studies on the management of OVCFs are warranted. A large, RCT to determine whether dynamic bracing is (cost)-effective for patients is a necessity to fill the gap in the conservative treatment of OVCFs. The results of such a trial are important for both patients and treating physicians (general practitioners, orthopaedic surgeons, trauma surgeons,

internal medicine specialists, rheumatologists, and physical therapists) who are consulted by OVCF patients, and currently have no treatment options for pain and disability except for pain medication.

### Doel van het onderzoek

In patients suffering from an OVCF dynamic bracing will improve quality of life with a positive effect on pain and sagittal spinal alignment. Dynamic bracing improves gait quality and balance, as well as physical activity, and decreases the recurrence rate of OVCFs. As such dynamic bracing is a cost-effective treatment for patients suffering from an OVCF.

### Onderzoeksopzet

All primary and secondary outcome parameters will be obtained at baseline, after 6 weeks, 3, 6 and 9 months, and at 1 year after baseline.

### Onderzoeksproduct en/of interventie

This is a multicenter, two-armed, parallel-group randomized controlled trial with a 1:1 allocation ratio consisting of an effect, economic and process evaluation. Postmenopausal women with a recent symptomatic thoracolumbar OVCF will be randomized into either the standard care or dynamic brace group. Standard care will consist of analgesics, anti-osteoporosis medication and optionally physical therapy at the discretion of the treating physician and according to current and local clinical guidelines. Patients allocated to the intervention group will receive a dynamic thoracolumbar brace, the Spinova Osteo® (Bauerfeind Benelux B.V.) in addition to standard care, which they will be instructed to wear for at least eight hours a day. Compliance to the brace treatment will be controlled via temperature sensors which will be implemented in the braces. Moreover, we will use patient diaries for optimal comparison between patients and to check adherence to the treatment. The Spinova Osteo® brace will be fitted by the local orthopaedic technician on the day of or within a few days after inclusion.

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Postmenopausal women;
- A symptomatic thoracolumbar osteoporotic vertebral compression fracture (less than 6 weeks old);
- Eligible for questionnaires with sufficient understanding of the Dutch written language.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Unstable vertebral fractures amenable for operative treatment;
- Neurologic deficit;
- Severe spinal deformity (scoliosis);
- Infection;
- Active cancer;
- Psychiatric or mental disease;
- Insufficient cognitive or language skills to complete the questionnaires.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

## Deelname

Nederland

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| Status: | Werving gestart |
| (Verwachte) startdatum: | 21-12-2020 |
| Aantal proefpersonen: | 98 |
| Type: | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Ja

**Toelichting**
The following end products will be made available for further research and verification: Documentation of the research process, including documentation of all participants, audiovisual material/ images, several versions of processed data and raw data. Data will be made accesible immediately after publication through the online DataHub infrastructure of MUMC+. To ensure the data and documentation is of sufficient quality to allow other researchers to interpret and reuse them, we will document the raw data; the data on which publications are based; documentation on the research; project proposal, approval from ethics
committees and approval from all stakeholders as specified in the ZonMw rules and regulations. During data collection we will incorporate as much restrictions and validation rules as possible to prevent data entry mistake and to increase the quality of the data. All data collection tools have an audit layer, all data changes will be logged (by whom, what and when). After data collection, a quality control will be performed. The use of an already existing meta-data standard (ISA) combined with the use of ontologies from various open ontologies provided by EBI's
Ontology Lookup Service, will assure that the interoperability of the data gathered in this project is optimal.

# Ethische beoordeling

Positief advies

| | |
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| Datum: | 30-06-2020 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54417
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL8746 |
| CCMO | NL74552.068.20 |
| OMON | NL-OMON54417 |

# Resultaten