Optimizing osteoporosis treatment outcomes: shared-decision making and adherence support program

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22858

Source
Nationaal Trial Register

Health condition

Osteoporosis

Sponsors and support

Primary sponsor: Maastricht University Medical Centre Maastricht (Netherlands).
Viecuri Medical Centre, Venlo (Netherlands).
Source(s) of monetary or material Support: ZonMw (Committee of the Rational Pharmacotherapy program, projectnumber 848016001)

Intervention

Outcome measures

Primary outcome

I) The effect of the MCAI on medication persistence.

II) The estimated lifetime cost-effectiveness of the MCAI compared to usual care for healthcare and societal perspective.

Secondary outcome

Secondary outcomes include: decision quality, medication initiation, alternative measures of adherence, health status (fracture events and mortality), quality of life and societal costs.

Study description

Background summary

Background

Osteoporosis remains a major public health problem. The prevalence of osteoporosis in the Netherlands was estimated at 16.1 per 1000 for women aged over 50 years and 1.9 per 1000 for men. The total economic burden of osteoporosis (including incident and previous fractures) was estimated at €824 million in the Netherlands in 2010 and fractures accounted for 26,300 quality-adjusted life years (QALYs) loss. Fractures are associated with increased morbidity and mortality and higher healthcare costs. Having had a recent fracture is the strongest risk factor for a (subsequent) fracture. In the Netherlands, nearly one in five patients with a non-vertebral fracture will sustain a subsequent fracture within five years and one in three will die. Subsequent fractures mainly occurred within the first two years after fracture, indicating the need to immediately prevent subsequent fractures. With increasing life expectancy, the incidence of osteoporotic fractures is estimated to increase by 40% in the Netherlands from 2010 to 2030 and the costs for osteoporotic fractures are projected to increase with 50% in the same period

Despite the fact that several drugs have been shown to be safe and effective in reducing fractures, adherence to medications remains poor and suboptimal. In the Netherlands, it was shown in 2011 that only 43% of patients starting oral medications were persistent after 1 year. Poor adherence leads to reduced effectiveness, with higher fracture rates than expected under full adherence and therefore decreased cost-effectiveness. A meta-analysis indicated that fracture risk increases by 30% with nonadherence compared to full adherence.

The Fracture Liaison Service (FLS) is advocated as the most appropriate approach for secondary fracture prevention. This approach is managed by a central coordinator, mostly a qualified osteoporosis nurse. In the Netherlands, several nationwide scientific committees have addressed the importance of initiating an FLS in hospitals in order to achieve adequate secondary fracture prevention, including including risk evaluation and differential diagnosis

Data from other studies suggested that several interventions are available to improve medication adherence including the use of a decision aid (DA), education/monitoring programs or automatic prescriptions. In addition interventions focusing on education

interventions revealed that tailored interventions with counselling sessions were shown to be effective in improving adherence to anti-osteoporosis medications. Involving patients in clinical decision-making and increasing patient support through nurse-led interventions could lead to improved satisfaction with therapy and hence medication adherence.

Study objectives

The current application proposes a 1-year sequential trial to assess the (cost-) effectiveness of a multi-component adherence intervention (MCAI) combining a patient DA, a nurse-led adherence support program and one extra FLS visit in osteoporotic patients with a recent fracture visiting a FLS clinic.

More specifically, the primary objectives of our study are:

to assess the effect of the MCAI on medication persistence and
to estimate the lifetime cost-effectiveness of the MCAI compared to usual care for healthcare and societal perspective

Medication adherence is defined as the process by which patients take their medications as prescribed, and is composed of initiation, implementation and discontinuation. Implementation with dosing regimen is difficult to assess in real-life settings without artificial use of Medication Event Monitoring System that could potentially affect adherence, and we therefore used persistence as primary outcome which is defined as the length of time between initiation and the last dose. Persistence is a more reliable measure and can be used as a proxy for adherence.

Design

A one-year sequential trial will be conducted to compare the effects of the MCAI with usual care in two FLS clinics. To avoid contamination of nurses' knowledge about the DA and the adherence support program after training, patients will be first assigned to the usual care arm and, upon reaching the targeted sample size, to the intervention arm. The DA/adherence support will be provided by trained nurses (and not by research assistant) as in real-life settings. As only one (or maximum two) nurse is working per center, we cannot do a consecutive random allocation because of contamination problems. A cluster RCT, randomizing FLS, would be the ideal design for the study objective. However, such design requires a large number of participating centers, a much higher sample size and therefore additional organizational and especially costs. Therefore, we have chosen for the second best option, a quasi-experimental design that is better suited for complex interventions. After the usual care group will be completed (including the follow-up visit of the last patient), nurses will be trained in the use of the DA and in adherence support in order to expose the intervention group to these strategies. A process evaluation and cost-effectiveness modelling study will also be conducted.

All patients ≥ 50years with a recent fracture having osteoporosis (assessed by DXA) who present at the FLS at MUMC+ and VieCuri Medical Centre with the need to start an anti-osteoporosis medication can be included. Patients need to be able to understand the Dutch language and be able to give informed consent. Patients with major comorbidities that are known to affect survival in the first year after fractures will be excluded.

Intervention

(1) Participants in the control group will receive usual care (that will be clearly protocolized and similar in all centers). So, a follow-up visit will take place between 6-8 weeks after the initial FLS visit. Patients will then be referred to the GP. The role of GP and pharmacist will be protocolized.

(2) The MCAI combines a patient DA, a nurse-led adherence support program and one extra FLS visit. In the intervention group, participants will then be guided in their decision by using a DA administered by the nurse (additional 5 minutes clinic times). At the 6-8 weeks usual control visit, the nurse will specifically inquire about therapy adherence using interviewing technique (additional 3 minutes time). In addition, an extra visit will be planned at 3-4 months.

A two-day workshop on DA/adherence support and their administration will be designed for the nurses from the three participating centers. First, a workshop on how to administer a DA and principles of shared-decision making will be given (about 6 hours). Nurses will receive background on the study, on the DA and on shared decision making, and will actively practice during the second part of workshop (role-play simulation). The second workshop (about 6 hours) that will aim to train nurses in finding solutions to improve adherence. The workshop will again include practical tasks.

Study objective

I) The Multi Component Adherence intervention (MCAI) will improve the (cost-)effectiveness of the treatment for osteoporosis at the Fracture liaison service.

II) The MCAI will improve the patient's involvement with the anti-osteoporosis treatment and the patients' confidence in in the decision which anti-osteoporosis treatment will be used.

Study design

Baseline, 4 months, 12 months.

(For patients who are treated with denosumab, there will be an additional timepoint in which persistence is measured at 24 months)

Intervention

The study entails a 1-year trial to assess the (cost-) effectiveness of a multi-component adherence intervention (MCAI) combining a patient DA, a nurse-led adherence support program and one extra FLS visit in osteoporotic patients with a recent fracture visiting a FLS clinic. The MCAI combines a patient DA, a nurse-led adherence support program and one extra FLS visit. In the intervention group, participants will then be guided in their decision by using a DA administered by the nurse (additional 5 minutes clinic times). At the 12-20 weeks usual control visit, the nurse will specifically inquire about therapy adherence using interviewing technique (additional 3 minutes time).

Contacts

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Eligibility criteria

Inclusion criteria

I) Recent fracture

II) Diagnosed with Osteoporosis (confirmed with dual-energy x-ray absorptiometry (DXA))

III) Eligable for anti-osteoporosis treatment

IV) Not used anti-osteoporosis medication in the last 12 months

V) Age higher than 50 years when included.

Exclusion criteria

I) Beeing treated for malignancies.

II) Incapable to comprehend the treatment and the study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	210
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-08-2018
Application type:	First submission

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
NTR-new	NL7236
NTR-old	NTR7435
Other	METC azM/UM : 2018-0575

Study results