The effect of support by telephone on compliance with medication by osteoporosis patients using bisphosphonates objectivied by systematic control of serum bonemarkers

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This study investigates to which degree osteoporosis patients taking weekly oral bisfosfonate medication are influenced by by three telephone support calls during the first year after starting this medication.To verify the results of patients` self...

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

Summary

ID

NL-OMON39186

Source
ToetsingOnline

Brief title
Telephone support, compliance osteoporosis medication, bonemarkers

Condition

- Bone, calcium, magnesium and phosphorus metabolism disorders
- Bone disorders (excl congenital and fractures)

Synonym
osteoporosis

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Fonds Stichting Wetenschappelijk Onderzoek Reinier de Graaf Groep Delft

Intervention

Keyword: compliance, osteoporosis, serumbonemarkers, support

Outcome measures

Primary outcome

1. Compliance: Patients`self-reported compliance using a validated questionnaire. The percentage of patients (outcome proprotion) which is compliant is in our expectations and based om literature in group 1 (at least) 30% higher than in group 2. This will support our assumption that supportive telephone contacts do increase compliance.
A Nivel questionnaire will be used to investigate patients` vision on medication and use of medication.

2. Serum bone-markers indicating bone-formation and bone-resorption bij laboratory examination (remaning percentage bone formation marker procollagen type 1 aminoterminal propeptide (s-P1NP) and remaining percentage bone-resorption marker C-terminal telopeptide (s-CTX).
Compliance is defined as completely compliant medication taking during the year of investigation, using the objectivity of calculation of a decline of at least 40% in the concentrations serum bone-marker compared to the level of bone-markers measured before the start of taking medication.

Secondary outcome

Reported side effects of the medication

Calcium and vitamin D substitutes

Attitudes towards taking medication

Study description

Background summary

In recent medical literature it becomes clear that more than half of the patients starting using a weekly oral bisfosfonates stops taking this medication during the first year. The principal motives which are brought forward is at one side the lack of conviction with the effectivity and on the other hand the fear for side effects of the medication in short and longer period. How compliance can be optimalised is not yet clear but previous studies underline the importance of a combination of persuasiveness and willingness to communicate.
In medical literature was shown that regular contact with the patients encourages compliance.
Modest own investigation based on patients` self-reported compliance showed that support given by telephone appears to increase compliance.

Study objective

This study investigates to which degree osteoporosis patients taking weekly oral bisfosfonate medication are influenced by by three telephone support calls during the first year after starting this medication.
To verify the results of patients` self report on compliance samples of serum bone markers will be used to objectify the results. Despite the lack of data on postmenopausal standards s-CTX and s-PINP are reliable markers and especcially investigated related to monitoring treatment of osteoporosis.

Study design

This study is divided in a randomised and a non-randomised part. Patients who meet the inclusion criteria are invited to participate in the randomised part of the study. Also two reference groups of patients wille be formed to observe the developments of bone markers.

Randomised:
This is a randomised clinical trial. Goups 1 and 2 form the arm of oral bisfosfonate users. Group 1 will have three telephone support calls and group 2 in this arm will not get these calls. Serum bone marker samples will be taken 5

times a year.

Non-randomised
Group 3 is a group of patients who receive because of medical reasons the bisfosfonate once yearly intravenous instead of once weekly oral . This is a group to observe the score and the development of bone markers influenced by a once yearly intravenous administration to be related to the groups on once weekly oral bisfosfonate medication. This group 3 will be contacted by telephone once shortly after the first administration to observe the experiences with the administration, possible side effects and the offered nursing service.
Group 4 is a group of osteopenic patients and is a reference group as well. This group is meant as a reference group for insight in the development of serum bone markers in a normal not osteoporotic population; the results of this group will be compared with the development of serum bonemarkers of patients being treated with (oral) bisfosfonates

Intervention

To group 1 and 2 a weekly oral bisfosfonate is prescribed.
Group 1 is offered support 3 times in the first year by a telephone call, group 2 will not get this support.

Study burden and risks

There is a low risk: it concerns the implementation of the regular treatment of patients with primary osteoporis .
The burden of investigation exists of taking bloodsamples of bonemarkers by venepuncture five times during the year.
The patient are asked to complete questionnaires at start en finish of the year.

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

There are two parts in the study: RCT and observational study.
For the RCT (group 1 and 2)
Female patients with osteoporosis to whom an oral bisfosfonate will be prescribed
Age 50-85 years
Legally capable
After agreement they sign the informed consent form. ;For the observational study (reference group 3):
Female patients with osteoporosis to whom an intravenous bisfosfonate will be prescribed for medical reasons
Age 50-85 years
Legally capable
After agreement they sign the informed consent form. ;For the observational study (reference group 4):
Female patients with osteopenia to whom no medication will be prescribed
Age 50-85 years
Legally capable
After agreement they sign the informed consent form.

Exclusion criteria

RCT:
Male patients
Age younger than 50 and older than 85 years
Legally incapable;Observational:

Age younger than 50 and older than 85 years
Legally incapable
No signed informed conscent form

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2012
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date:	16-01-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	26-03-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL35164.098.11