Osteoporosis, Osteoarthritis and the influence of bisphosphonates, an explorative study

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Is the radiological, histological and biomechanical condition of bone altered after long term bisphosphonate treatment in bone that is subjected to either compressive of distractive forces.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational non invasive

Summary

ID

NL-OMON36051

Source
ToetsingOnline

Brief title
Influence of bisphosphonates on bone

Condition

- Bone disorders (excl congenital and fractures)

Synonym
fragile bones, osteoporosis

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Aanvraag ingediend bij het Annafonds

Intervention

Keyword: bisphosphonate, osteoarthritis, osteoporosis

Outcome measures

Primary outcome

Main study parameters are differences in radiological, histological and

biomechanical results between the two groups.

Secondary outcome

not applicable

Study description

Background summary

Concerning the effects of bisphosphonates in humans, little research is done in regions that are subjected to compression and distraction forces. Almost all human studies are done on the iliac bone, a fairly nonweightbearing area of the human body. To get insight in the mechanism of action of bisphosphonate in a region with high bone turnover, the femoral neck can be used, because of the compression (calcar) and distraction (superior neck) forces.

Study objective

Is the radiological, histological and biomechanical condition of bone altered after long term bisphosphonate treatment in bone that is subjected to either compressive of distractive forces.

Study design

This study is a retrospective follow-up study, comparing the outcomes of radiological, histological and biomechanical testing of bone in the femoral neck region.

Study burden and risks

Patients from both groups will have no different workup before their operation than normal. The only difference is a DEXA scan performed of both hips and the

lumbar spine prior to the operation of both groups. Therefore, only one extra visit to the hospital has to be made. DEXA has a low radiation exposure and risks are negligible.

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

Patients who are selected to get a total hip prosthesis implanted at Reinier de Graaf Gasthuis. Patients are 18y and older, willing to participate and compos mentis.

Exclusion criteria

They do not suffer systemic disease affecting the bones or have a history of malignancy.

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Date:	26-08-2011
Application type:	First submission
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	NL37068.098.11