

Calcium intake and osteoporosis in postmenopausal women with an intellectual disability

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We examine whether the calcium intake from food in postmenopausal women with an ID suffice to the quantity calcium intake that is advised by the NHG-standard. If the conclusion of this study will be that the population is eating less calcium than is...

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

Summary

ID

NL-OMON34712

Source

ToetsingOnline

Brief title

Calcium osteoporosis postmenopausal women intellectual disability.

Condition

- Bone, calcium, magnesium and phosphorus metabolism disorders

Synonym

Osteoporosis

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus Universiteit Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Calcium intake, Intellectual Disability, Osteoporosis, Postmenopausal

Outcome measures

Primary outcome

Calcium intake from food, supplement and medication was obtained from a food questionnaire. The attendant of the client will fill in this questionnaire. In this questionnaire there will be asked how many cups of food products with calcium the patient eats e.g. milk, cheese and yoghurt. These cups will be converted in grams calcium.

The quality of the calcaneus (heel bone) will be measured with a Lunar Achilles Insight, which is a portable device that measures the bone quality of the heel with ultrasonometry. Evidence supports the value of densitometry at the heel as the optimum peripheral site for fracture risk assessment, due to the heel's easy accessibility, metabolically active bone and high trabecular content.

Secondary outcome

The secondary variability*s are the age, the level of development, the mobility, sort of residence and guidance of the client. The level of development is subdivided in profound mental retardation (IQ below 20), severe mental retardation (IQ is 20 - 34), moderate mental retardation (IQ is 35 - 49) and mild mental retardation (IQ is 50 - 69).

The mobility is subdivided in be able to stand or walk and not be able to stand or walk.

The sort of residence is subdivided in living in a community, living in a private apartment in a community, in a family replacement residence.

The guidance is subdivided in guided but independent living or independent living.

With these variability*s we want to answer the question if there is a relation between the calcium intake and the secondary variability*s.

Study description

Background summary

In this study we determine the calcium intake from food, supplements or medication in postmenopausal women with an intellectual disability (ID). We also determine the prevalence of osteoporosis in the same group.

Osteoporosis is characterized by low bone mass and micro architectural deterioration of bone tissue, which leads to an increase in bone fragility with a resultant susceptibility to fracture.

The factor that leads to osteoporosis in women is also because of the decrease of estrogens in the menopause. Therefore, the Dutch federation of general practitioners (Nederlandse Huisartsen Genootschap Standard) gives the advice to eat daily 1000 to 1200mg of calcium. It seems to be that Dutch women at the age of 50 years and older, eat 100 to 250mg less calcium than is advised.

Little is known about the prevalence of the calcium intake in postmenopausal women with an intellectual disability. But it is known that the prevalence of osteoporosis is higher in women with an ID. Women with physical disabilities that impair mobility have many risk factors for osteoporosis. Such women often are non-ambulatory, frequently taking medications that increase the risk of osteoporosis, and may have lifestyles that do not offer optimal exposure to sunlight, which can predispose to vitamin D deficiency.

Study objective

We examine whether the calcium intake from food in postmenopausal women with an ID suffice to the quantity calcium intake that is advised by the NHG-standard. If the conclusion of this study will be that the population is eating less calcium than is advised, a simple advise and intervention can follow.

Study design

This study has a cross-sectional observational design, where there will be no

interventions.

Study burden and risks

The attendant of the client will answer the food questionnaire. It will take at the very most 30 minutes. This depends on how acquainted the attendant is with the food pattern of the client.

The measurement of the bone quality with the Lunar Achilles Insight will take five minutes per client. The Lunar Achilles Insight is non-invasive and free from radiation. The testing is simple and fast and does not give discomfort to the client. The measurements can also be executed at feet that are mildly dysmorphic. The measurements are less suitable for people with severe motor disabilities or severe dysmorphic feet. These measurements can be invalid. There are no medical risks for the client. When the conclusion is that the client has a reduced intake of calcium or a reduced bone quality, advise about interventions and further research will be giving to the permanent doctor of the client.

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

Women older than 50 years

Living in organizations for people with an intellectual disability

Women who have a Down syndrome are included at an age of 40 years and older.

Exclusion criteria

Therapeutic use of oestrogen en bisfosfonate

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 07-09-2010

Enrollment: 348

Type: Actual

Ethics review

Approved WMO

Date:	18-06-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL31391.078.10