Prevalence of low bone mineral density in residents of a long-term facility care centre for people with refractory epilepsy, intellectual disability and long-term use of anti-epileptic drugs: a cross-sectional cohort study.

Published: 07-07-2009
Last updated: 06-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational invasive

Summary

ID

NL-OMON33809

Source
ToetsingOnline

Brief title
Epilepsy, AEDs and prevalence of low BMD:a cross-sectional cohort study

Condition

- Bone disorders (excl congenital and fractures)
- Seizures (incl subtypes)

Synonym
low bone mineral density, Osteoporosis

Research involving
Human

Sponsors and support

Primary sponsor: Epilepsiecentrum Kempenhaeghe
Source(s) of monetary or material Support: Epilepsiecentrum Kempenhaeghe

Intervention

Keyword: Anti-epileptic drugs, Bone mineral density, Intellectual disability, Osteoporosis

Outcome measures

Primary outcome

Main study parameters: The main study parameter is the BMD expressed as T-score

(number of standard deviations below peak bone mass) measured by DEXA scan and

QUS.

Secondary outcome

The secondary study parameters are the outcome of the bone turnover parameters,

the outcome of the QUS, the fracture history, and the number of vertebral

fractures.

Study description

Background summary

Chronic treatment with anti-epileptic drugs (AEDs) is associated with reduced bone mineral density (BMD), which may underlie the two to sixfold increase in fracture rates observed in patients with refractory epilepsy. In patients with an intellectual disability (ID) low BMD is found more frequently than in a general population. In patients with an ID ánd epilepsy, multiple risk factors for low BMD and increased fracture rates are present creating a high risk for this specific subpopulation. In spite of the growing body of literature which strongly recommends screening as standard part of good clinical practice of patients with epilepsy, routine screening for BMD loss among people with an ID and epilepsy has not been practiced, partly because the exact prevalence of low

BMD in patients with ID and epilepsy is not known.

Study objective

The main objective of this study is to determine the prevalence of low BMD measured with dual-energy X-ray absorptiometry (DEXA) and quantitative ultrasonography (QUS) in Providentia (a residential care facility for persons with refractory epilepsy often in combination with an intellectual disability) and to identify risk factors for low BMD.

Study design

Observational cross-sectional cohort study.

Study burden and risks

All patients are seen in their own living environment in Providentia during one on-site visit. Using a standardized data collection form information is abstracted from each chart. Actual weight and height will be measured if not available in patient*s chart. A questionnaire to estimate patient*s daily calcium intake over 3 days is filled in cooperation with the patient*s direct caretakers. Each patient will have one blood sample tested. Also a DEXA scan and a QUS for measuring BMD is done. QUS is a non-invasive bone measuring method without any radiation involved. DEXA is also non-invasive and has a very low radiation burden, approximately 10 times lower than a chest radiograph [7]. The burden and risks associated with participation in this study are therefore considered minimal. The patient*s general physician is notified if osteoporosis is found. This to ensure further investigation, risk assessment and treatment of the osteoporosis in the best interest of the patient.
In people with refractory epilepsy and ID multiple risk factors are present for developing BMD loss and associated fractures, and are therefore considered a subpopulation at an especially high risk. Consequently, results of investigations in patients with epilepsy without ID cannot be extrapolated to this specific high risk group.
The data on epilepsy, AEDs and low BMD justify systematic screening with DEXA and laboratory investigations. Taking into account the growing body of evidence, nowadays screening is strongly advised by many authors in the field. If this research project would not take place, all the residents of Providentia would still be screened for the presence of osteoporosis and osteopenia with a DEXA scan and laboratory investigations.
Therefore, the specific extra measurements that will be done for this research project are:
1) an ultrasonography of the calcaneus (non-invasive, no radiation load, duration of 10-20 seconds),
2) drawing of 2 tubes of blood extra (the venapunction will take place at the same time of the 6-monthly blood check ups of the residents, so no extra

venapunction will be done).
3) a food frequency questionnaire will be completed in cooperation with the direct caretakers of the residents.
All the 3 above mentioned measurements will take place during an on-site visit on the residential facility care centre.

Therefore the burden associated with participation is considered low and the all the three measurements necessary for this research project are of non-invasive nature.

The results of these measurements will facilitate the establishment of standardized screening and treatment protocols for specific at risk subpopulations and help to achieve the long-term goal of preventing low BMD in this particular population.

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

All residents of Providentia (a residential facility care centre for people with refractory epilepsy) aged 18 years and older.
Inclusion criteria:
- Diagnosis of epilepsy
- Use of AEDs
- Age 18 years and older

Exclusion criteria

Exclusion criteria:
- No diagnosis of epilepsy
- No use of AEDs
- Age younger than 18 years
- Pregnancy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-08-2009
Enrollment:	180
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	09-07-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL26095.068.09