Determination of risk factors for developing osteoporosis in COPD GOLD II patients. A case control study to identify possible risk factors for developing osteoporosis in COPD GOLD II patients.

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Determination of possible risk factors for developing osteoporosis in GOLD II COPD patients.

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

Summary

ID

NL-OMON31334

Source
ToetsingOnline

Brief title
Osteoporosis in GOLD II COPD patients.

Condition

- Bone disorders (excl congenital and fractures)
- Bronchial disorders (excl neoplasms)

Synonym
bone decalcification. AND chronic bronchitis, emfysema, Osteoporosis

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: maatschap longziekten

Intervention

Keyword: COPD, GOLD classification, Osteoporosis

Outcome measures

Primary outcome

Determination of possible risk factors for the developing of osteoporosis in

COPD GOLD II patients.

Bone mineral density (T-score and Z-score): osteoporosis vs no osteoporosis

• BMI/VVMI

• Emfysema/chronic bronchitis (HRCT scan and diffusion capacity)

• Hyperinflation

• Physical capacity

• Nutritional status

• Infectious parameters (CRP, ESR, leucocytes)

• Use of medication

Secondary outcome

Not applicable

Study description

Background summary

Osteoporosis is characterized by low bone mass and a changed micro architecture leading to increased bone fragility and an increased fracture risk. The etiology of osteoporosis in COPD patients is complex and multifactorial. There are not mana large studies investigating the causes of osteoporosis in COPD patients. Most of the studies investigate patients with more serious COPD.

Study objective

Determination of possible risk factors for developing osteoporosis in GOLD II COPD patients.

Study design

A case control study. Patients with COPD GOLD II (diagnosis according to ATS guidelines and devided according to GOLD-classification) who participated in the study "osteoporosis in COPD patients" or who visit the outpatients clinic of pulmonology of the Catharina Hospital Eindhoven will be asked to participate. Patients will answer the questionnaire, do a 6-minute walking distance, will have a bio-impedance measurement, will get a blood test, an X-ray of the vertebrae, a HRCT and a DEXA-scan (or the previously collected data will be used)
Patients with osteoporosis will be matched with patients without osteoporosis (matched by age and gender). By univariate and myltivariate analyses the collected data will be analysed to determine possible risk factors for the development of osteoporosis in COPD GOLD II patients.

Study burden and risks

Patients will need to come to the hospital once or twice for a six minute walking distance, bio-impedance measurement, X-ray of the spine, to draw some blood and to have a High resolution CT made. Also they will have to go to the Diagnostic Centrum Einhoven to have a DEXA-scan made.
So the burden is relatively low and also the risks associated with drawing blood and having a CT-scan and DEXA-scan taken are low.
For some patients the tests are already done so the burden and risk will be none.

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

Age >=40
COPD GOLD II patients
Written permission (informed consent)
Men and women

Exclusion criteria

Age < 40
COPD GOLD I, III or IV
No permission

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-09-2007
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	12-09-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL18223.060.07