

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Bone disorders (excl congenital and fractures)
<b>Study type</b>	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 many 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 divided 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 multivariate 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 Eindhoven 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**

### **Public**

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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  $\geq 40$

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