# Bone Mass in Patients with Familial Adenomatous Polyposis

Published: 17-07-2008 Last updated: 07-05-2024

To assess the skeletal health of FAP patients.

**Ethical review** Approved WMO

**Status** Pending

Health condition type Chromosomal abnormalities, gene alterations and gene variants

**Study type** Observational invasive

# **Summary**

#### ID

NL-OMON32091

**Source** 

ToetsingOnline

**Brief title** 

**BOMFAP** 

#### **Condition**

- Chromosomal abnormalities, gene alterations and gene variants
- Benign neoplasms gastrointestinal
- Gastrointestinal neoplasms benign

#### **Synonym**

high bone mass, osteopetrosis

#### Research involving

Human

## **Sponsors and support**

Primary sponsor: Leids Universitair Medisch Centrum

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

#### Intervention

**Keyword:** Bone mass, Familial Adenomatous Polyposis, Fractures, Osteomas

#### **Outcome measures**

#### **Primary outcome**

The potential effect of genetic abnormalities in the APC gene on bone mineral density in patients with Familial Adenomatous Polyposis (FAP).

#### **Secondary outcome**

The potential effect of genetic abnormalities in the APC gene in FAP patients on

- bone and mineral metabolism
- prevalence of fractures
- prevalence of joint disorders.

# **Study description**

## **Background summary**

The rationale for this pilot study is based on the increasing evidence linking deregulated canonical Wnt signaling pathway with abnormal bone mass and with increased incidence of skeletal disease. FAP patients carry APC mutations that will constantly result in a constitutively active Wnt signaling. The question arises whether APC, the key intracellular gate-keeper controlling Wnt/ $\beta$ -catenin turnover, is ultimately involved in the regulation of bone mass.

#### Study objective

To assess the skeletal health of FAP patients.

#### Study design

All investigations will be conducted in the LUMC:

- medical history
- physical examination
- skeletal scintigraphy
- laboratory investigations for bone and mineral metabolism
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- dual X-ray absorptiometry (DEXA) to measure the bone mineral density
- in case of possible skeletal pathological condition(s) detected upon physical examination, skeletal scintigraphy or DEXA, an X-ray of the region(s) of interest will be performed to further investigate and confirm the nature of the lesion(s).

## Study burden and risks

Not applicable.

## **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

- Genetically and histologically documented diagnosis of FAP
- Informed consent

#### **Exclusion criteria**

- Use of bisphosphonates in the last 3 years
- Current use of PTH (1-34 or 1-84)

# 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: Pending

Start date (anticipated): 01-06-2008

Enrollment: 25

Type: Anticipated

# **Ethics review**

Approved WMO

Application type: First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

# **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 NL21922.058.08