Bone Mass in Patients with Familial Adenomatous Polyposis

Published: 17-07-2008
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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/β-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

- 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
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA, Leiden
Nederland
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA, Leiden
Nederland

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