The Effect of Inflammation on Bone Cells

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal infections
Study type	Observational invasive

Summary

ID

NL-OMON31917

Source
ToetsingOnline

Brief title
The Effect of Inflammation on Bone Cells

Condition

- Gastrointestinal infections
- Fractures

Synonym
inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: inflammation, Inflammatory Bowel Disease, osteoblasts, osteoclasts

Outcome measures

Primary outcome

osteoblast proliferation, osteoblast differentiation, osteoclastogenesis,

osteoclast function and bone histomorphometry

Secondary outcome

NA

Study description

Background summary

Decreased bone mineral density (BMD) is a common phenomenon in chronic inflammatory diseases like inflammatory bowel disease (IBD), and the prevalence of osteoporosis complicating these diseases has truly been underestimated. The pathogenesis of bone loss and osteoporosis in patients with chronic inflammatory diseases is complex. Traditionally, IBD involves calcium and vitamin D malabsorption caused by decreased ileal function and corticosteroid treatment. More recently, the inflammatory process has been proposed to play a central role in both local and systemic bone loss. However, the exact effect of inflammation on bone loss still remains unclear.

Study objective

This study aims to gain insight into the effect of inflammatory factors on bone metabolism. For this purpose we formulated the following research questions:

1. Which circulating inflammatory factors play a central role in the pathogenesis of general and local osteoporosis in patients with chronic inflammatory diseases?
2. Can the pathogenesis of general and local osteoporosis be inhibited by blocking specific inflammatory factors, comparable to the inhibition of TNF alpha by infliximab?
3. Is there a difference in the osteoclastogenesis and/or osteoclast function between patients with chronic inflammatory diseases and healthy controls?

Study design

cross-sectional

Study burden and risks

A transiliac bone biopsy may involve pain and discomfort. There is some risk of bruising and wound infection, but serious complications are very rare. The drawing of a blood sample may involve some discomfort.

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

1. Men and women between the age of 18 and 50 years
2. Informed consent
3a. Patients suffering from Crohn*s disease of at least 3 months duration, confirmed by radiography, endoscopy and histology (according to the Lennard-Jones criteria ; Lennard-

Jones 1989).
3b. Patients suffering from Ulcerative Colitis of at least 3 months duration, confirmed by radiography, endoscopy and histology (according to the Lennard-Jones criteria)
4. a BMI between 18-30

Exclusion criteria

1. Co-morbidity influencing bone metabolism
- Renal insufficiency (creatinin clearance < 40 ml/min)
- untreated hypo- / hyperthyroidism (stabily treated hypothyroidism may be included)
- Paget*s disease or other metabolic bone diseases, Cushing*s disease or hyperprolactinemia
2. Patients who have received calcitonin, bisphosphonates and strontium within 1 year
3. Use of corticosteroids current use and in the last 3 months in case of longterm use or in the last 6 weeks in case of induction therapy
4. Patients who have been treated with anti-TNF in the last 6 months
5. Use of antitrombotic agents
6. Patients who are pregnant, breast-feeding or menopausal

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-07-2008
Enrollment:	55
Type:	Actual

Ethics review

Approved WMO Date:	08-07-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL23103.029.08