Measurement of biochemical markers of bone turnover in patients with bilateral sagittal split osteotomy

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Primary Objective: - Are there mesurable changes in biochemical markers after BSSO in serum(CTX, P1NP, BALP, Osteocalcine, Calcium, vit D. CRP, BSE, leucocyten, IL6, creatine) and in urine(hydroxylysylpyridinoline en lysyspyridinoline)? - Can serum...

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

Summary

ID

NL-OMON36318

Source
ToetsingOnline

Brief title
Measurement of biochemical markers of bone turnover in patients with BSSO

Condition

- Bone disorders (excl congenital and fractures)

Synonym
bone specific markers in urine and serum

Research involving
Human

Sponsors and support

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

Intervention

Keyword: biochemical markers, bone, BSSO, mandible

Outcome measures

Primary outcome

Primary Objective:

- Are there mesurable changes in biochemical markers after BSSO in serum(CTX,

P1NP, BALP, Osteocalcine, Calcium, vit D. CRP, BSE, leucocyten, IL6,

creatine) and in urine(hydroxylysylpyridinoline en lysyspyridinoline)?

- Can serum and urine biochemical markers predict bone remodeling?

Secondary outcome

None

Study description

Background summary

In certain pathological diseases of the bones there are bone related biochemical parameters. There are studies in which osteomyelitis of the mandible is diagnosed and followed during treatment through bone-specific biochemical markers (Springer et al. A new method of monitoring osteomyelitis Int. J. Oral Maxillofac. Surg. 2007;36: 526-532). In case of an osteomyelitis of the mandible it is often possible to diagnose a patient based on clinical examination and plain x-ray of CT-scan. Treatment of osteomyelitis is often long-lasting oral antibiotics, sometimes combined with surgical sequestration. It is however very difficult to measure to which extent there is still an active infection. The choice to stop or continue the treatment with antbiotics is therefore difficult.
The report that biochemical markers for bone turnover can be used in the diagnostic process and treatment of osteomyelitis of the mandible is clinically relevant. There are however no normal values in the remodeling or recovery of mandible bone. There are normal values of other long bones as the femur or radial bone. Due to the relative small size of the mandible it is however questionable whether remodeling of this bone is even measurable at all. In normal infection of the mandible or maxilla the usable infection parameters

(CRP, leucocytes) are seldom above normal. This is why the current investigation will be if bone specific biochemical markers change measurable during the process of bone recovery in a clinical model. The data from this research will be a reference for future research in bone specific biochemical markers in pathological conditions. As a model in this study we have chosen for the bilateral sagittal split osteotomy (BSSO) of the mandible.
During a BSSO the length of the mandible is being corrected. The mandible is bilaterally split and fixated in its new position (often more ventral). After this BSSO the broken mandible will remodelate into a complete mandible. This takes a maximum of 3 months according the normal fracture healing.
During remodeling of the mandible several biochemical markers will be released to the blood and filtered in the urine. This study will measure whether the biochemical markers in serum (CTX, P1NP, BALP, Osteocalcine, Calcium, vit D. CRP, BSE, leucocyten, IL6, creatine) and urine (hydroxylysylpyridinoline en lysylpyridinoline) undergo changes that fit a systemic change.

Study objective

Primary Objective:
- Are there mesurable changes in biochemical markers after BSSO in serum(CTX, P1NP, BALP, Osteocalcine, Calcium, vit D. CRP, BSE, leucocyten, IL6, creatine) and in urine(hydroxylysylpyridinoline en lysyspyridinoline)?
- Can serum and urine biochemical markers predict bone remodeling?

Study design

Cohort study

Study burden and risks

Simultaneously with the regular post-operative controle there will be three vena-punctures. Next to that patients will collect midstream morning urine for analysis at home.

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

Patients for Bilateral Sagittal split Osteotomy
Over 18 years old

Exclusion criteria

Renal and liver function problems
Active treatment with growth hormone
Patients with Hormone replacement therapy
Breastfeeding
Pregnancy
The use of anti-epileptics
Astma patients that use inhalation steroids
The use of anticoagulentia

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	31-01-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL33598.042.11