The use of Progentix TCP (beta-tricalciumphosphate) as a bone substitute in defects originated from curettage of benign bone tumors

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In patients with benign bone tumors, the defect originated from curretage of the tumor, will be filled with Progentix TCP. The bone regenerative capacity of Progentix TCP will be compared to the capacity of autologous bone (the golden standard)....

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON31641

Source
ToetsingOnline

Brief title
Progentix TCP as bone substitute after curettage of benign bone tumors

Condition

- Bone disorders (excl congenital and fractures)
- Skeletal neoplasms benign
- Bone and joint therapeutic procedures

Synonym
benign bonetumors, bonecysts

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bone cysts, bone substitutes

Outcome measures

Primary outcome

After 6 weeks, 3 months, 6 months, 1 year and 2 years, the amount of bone

formed by "creeping substitution" in the bone defect will be assessed by means

of X-rays.

Secondary outcome

not applicable

Study description

Background summary

The human body is not capable of repairing bone defects above a certain size by itself. This is only possible when the defect is filled with a temporary substance. Currently, autologous bone is the golden standard for filling defects originated from curretage of benign bone tumors. Often patients have longlasting pain at the donorsite (the site where autologous bone was taken). Progentix BV has recently developen a novel b-tricalciumfosfate, which has the property to actively induce bone formation by attracting patient-own stemcells and stimulating the osteogenic differentiation of these cells.
Our hypothesis is, that Progentix TCP is at least as good a bone substitute as autologous bone, while at the same time, the occurance of pain at the donorsite is diminished.

Study objective

In patients with benign bone tumors, the defect originated from curretage of the tumor, will be filled with Progentix TCP. The bone regenerative capacity of Progentix TCP will be compared to the capacity of autologous bone (the golden

standard). When Progentix TCP indeed has the same qualities as autologous bone, the harvesting of autologous bone and the accompanying complications can be prevented in the future.

Study design

In a pilot study ten patients will be treated with Progentix TCP after curretage of a benign bone tumor. After 6 weeks, 3 months, 6 months, 1 year and 2 years X-rays will be made to determine whether the bone defect is filled with patient-own bone by means of "creeping substitution".

Intervention

Following curettage of the benign bone tumor the defect will be filled with Progentix TCP. So, a surgical intervention will take place.

Study burden and risks

Possible delayed closing of the bone defect via creeping substitution with living patient-own bone.

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

benign bonetumors to be treated with curettage

Exclusion criteria

Use of Progentix TCP synthetic cancellous bone void filler is CONTRAINDICATED in the presence of one or more of the following clinical situations: Malignant bonetumors, In case of severe metabolic or systemic bone disorders that affect bone or wound healing, In case of acute and chronic infections in the operated area (soft tissue infections; inflamed, bacterial bone diseases; osteomyelitis), In case of treatment with pharmaceuticals interfering with the calcium metabolism.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-12-2008
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO Date:	16-06-2009
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	NL15256.044.08