

# 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 curettage 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)....

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Bone disorders (excl congenital and fractures)
<b>Study type</b>	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 curettage 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 curettage 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 curettage 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**

### **Public**

Medisch Spectrum Twente

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### **Scientific**

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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