Surgical use of 3D printed cages as adittion for the filling of large bone defects, a randomised controlled trial

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To investigate whether the addition of a custom made 3D printed scaffold to standard treatment increases healing and decreases the need for secondary surgery in segmental defects of long bones with a length of more than 5 cm compared to the standard...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON56816

Source
ToetsingOnline

Brief title
SCAFFOLD trial

Condition

- Bone and joint therapeutic procedures

Synonym
Critical size bone defect, fracture

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: TKI,Osteopore

Intervention

Keyword: Bone defect, polycaprolactone, Scaffold, tricalciumphosphate

Outcome measures

Primary outcome

Follow-up is scheduled at regular intervals; six weeks, twelve weeks, six months, and one year. The primary study endpoint is the volume of newly formed bone at the defect site, based on CT-scans at six months follow-up.

Secondary outcome

Secondary outcome parameters are secondary interventions, quality of life (EQ-5D5L, PROMIS), lower extremity function scale or disabilities of the arm, shoulder and hand (DASH) questionnaire if applicable, necessary reinterventions, recurrence/persistence of infection, burden-of-disease and cost-effectiveness, including the Medical Consumption Questionnaires (MCQ) and Productivity Cost Questionnaire (PCQ).

Study description

Background summary

Bone defects have a devastating impact on quality of life. The affected limb cannot be used and the subsequent lack of mobility results in a low health-related quality of life. Treatment of bone defects is challenging, especially when infection is present, and frequently ends in an amputation. To restore bone continuity, bone regeneration has to occur and that requires several biological and mechanical components. A good soft tissue coverage, the presence of cells, growth factors and a scaffold are all prerequisites for bone regeneration in an environment that has to be well vascularized and free of infection. Nowadays, bone autograft supplemented with bone marrow stem cells and bone growth factors is the gold standard to improve healing in traumatic bone defects. However, in larger defects (>5cm) the treatment remains challenging due to limited scaffolding and treatment-resistant infection.

Application of an innovative, custom made, 3D-printed cage made of poly-*-caprolactone with ß-tri-calcium phosphate (PCL/TCP) has the potential to improve the clinical outcome substantially.

Study objective

To investigate whether the addition of a custom made 3D printed scaffold to standard treatment increases healing and decreases the need for secondary surgery in segmental defects of long bones with a length of more than 5 cm compared to the standard treatment, which consists of a combination of autologous bone, stem cells, osteoconductive materials and growth factors.

Study design

Prospective, single-center randomized clinical trial, single blinded.

Intervention

The control group will receive the standard treatment for these defects in our center. This treatment consists of a two-stage surgical procedure called the Induced Membrane Technique (IMT). During the first stage, the surgical site is debrided and a cement spacer is placed to initiate the formation of a membrane around the spacer; a physiological response to the implanted foreign body (the cement spacer). If deemed necessary, soft tissue coverage via free flap transfer is performed as well. In the second stage, the spacer is removed and autograft bone, Reamer Irrigator Aspirator (RIA) derived autograft and Bone Marrow Aspirate Concentrate (BMAC), and factor P-15 (iFactor, Cerapedics, Westminster, USA) are applied in the bone defect area. The experimental group will receive the treatment as described before, combined with a 3D-printed scaffold consisting of PCL/TCP (Osteopore, Taman Jurong, Singapore).

Study burden and risks

The choice for the timing of the endpoints is based on regular care in order to limit the burden for participants. This is also the case for all radiological examinations including the CT scan at six months. The study requires 2 additional CT scans, the radiation exposure of these scans is lower than the amount of natural radiation humans are exposed to every year.
Participants will be requested to fill out the above described questionnaires at each follow-up moment; six weeks, twelve weeks, six months, and one year. We classify the burden for these questionnaires as minimal in accordance with previous evaluations by the local ethical committee. The main risks for the participants are all related to the medical condition of the bone defect and are, as we foresee, not related to the study participation. In general, these risks are infection at the surgical site, persistent/permanent pain at the surgical site, sensory loss or disturbance at the surgical site and, when

utilized, free flap failure.

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

Posttraumatic critical size bone defect of 5 or more centimeters of a long bone after debridement
Age over 18 years
Informed consent for surgical treatment and participation in the study

Exclusion criteria

Segmental bone defects < 5 cm in length after debridement
Inability to understand the Dutch language
Inability to comply with follow-up
Untreated metabolic comoribities (such as diabetes and osteoporosis)
Patients with cancer or bone defects due to a malignancy
Unable to participate judged by treating physician
Paraplegia
Interoperative exclusion due to instrumental problems

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2024
Enrollment:	26
Type:	Anticipated

Medical products/devices used

Generic name:	aXOpore Custom Made Device (CMD) polycaprolactone tricalcium phosphate scaffold
Registration:	No

Ethics review

Approved WMO

Date:	12-06-2024

Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL84289.068.23
Other	OMON register, te vinden onder de titel van de studie