# A Randomized Intra-Patient Controlled Trial of MagnetOsTM Granules vs. Autograft in Instrumented Posterolateral Spinal Fusion

Published: 30-05-2018
Last updated: 10-01-2025

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| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Joint disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON48595

**Source**
ToetsingOnline

**Brief title**
MaxA study

### Condition

- Joint disorders
- Nervous system, skull and spine therapeutic procedures

**Synonym**
spinal fusion, Spondylodesis

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** Industrie,Kuros Biosciences BV (restricted research grant)

## Intervention

**Keyword:** bone graft, ceramic, RCT, spinal fusion

## Outcome measures

### Primary outcome

The primary efficacy outcome is the rate of successful posterolateral spinal fusion after one year, assessed on CT-scans. Non-inferiority of the MagnetOsTM condition compared to the autograft condition will be assessed using a McNemar*s test. The primary safety outcome is the number and nature of (serious) adverse events related to the surgical procedure compared to control populations from literature.

### Secondary outcome

Secondary outcomes are the comparison to its predicate (AttraX® Putty), relation between posterolateral fusion and interbody fusion after one-year, posterolateral spinal fusion rate after two years, relevance of iliac crest donor site pain and the incidence of long-term complication and relation with risk factors in the combined population of this study and the AxA study.

# Study description

### Background summary

Posterolateral spinal fusion is currently performed by using large amounts of autologous bone graft. Drawbacks of bone grafting include the need for an

additional surgical procedure, limited supply, sub-optimal bone quality in osteoporotic patients and harvesting morbidity, which led to the development of numerous bone graft substitutes. Recently, we completed enrollment and one-year follow-up for a clinical trial to evaluate such a bone graft substitute (AxA study, METC number 13-192). The product, AttraX® Putty, is a bioresorbable tricalcium phosphate (TCP), mixed with a fast resorbing polymer carrier to improve surgical handling. The preliminary results are promising in terms of no adverse events related to the product and a first impression of similar fusion rates. However, especially in more challenging conditions, both the autograft and the material may resorb too fast and bone formation by induction was limited. Recently an improved version of the TCP granules has been developed, named MagnetOsTM Granules, which has shown favorable results especially of these resorption and induction characteristics in pre-clinical studies. MagnetOsTM Granules are CE-marked (2115660CE01) and received 510(k) clearance from the US Food and Drug Administration (K161859).

## Study objective

The primary objective is to demonstrate non-inferiority of MagnetOsTM Granules compared to autograft in instrumented posterolateral spinal fusion, in terms of efficacy and safety by means of an intra-patient model.

## Study design

This study is designed as a multicenter, observer blinded, randomized, controlled non-inferiority trial with intra-patient comparisons.

## Intervention

According to a randomization scheme, one side of the spine will be grafted with the MagnetOsTM Granules and the other side with bone harvested from the iliac crest and local bone. The rest of the surgical procedure will be according to standard care.

## Study burden and risks

Patient burden and risks are expected to be minimal. The first-year follow-up will be according to the standard of care at the UMC Utrecht. Additional procedures for this study include the completion of short patient reported outcome measurements at five time points and, depending on the local follow-up protocol, a CT-scan at one-year follow-up and/or X-ray at two years follow-up. In case the one-year CT-scan shows a doubtful fusion or non-union in any of the relevant levels, an additional CT-scan will be made at two years follow-up. Based on pre-clinical investigations, and the results of the AxA study, the risk for inferior performance of MagnetOsTM Granules is expected to be minimal. Even if this appears to be the case, it will have minimal consequences for the

patient as the other side of the spine will be fused with autologous bone graft and the spine is rigidly instrumented with screws and bars. All patients may benefit from the study in terms of reduced surgical time, since only half of the required bone graft will be harvested from the iliac crest.

## 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

• To be treated with instrumented posterolateral thoracolumbar spinal fusion with the use of iliac crest bone, with or without additional posteriorly inserted interbody devices (PLIF, TLIF), because of (1) deformity, (2) structural instability and/or (3) expected instability as a result of decompression for spinal stenosis;
1. Deformity is defined as a scoliosis in the coronal plane of >20° and/or a sagittal balance disturbance according the SRS/Schwab classification on standardized standing full spine

radiographs;
2. Preoperative instability is defined as a progressive angular deformity or spondylolisthesis in standing radiographs;
3. Decompression for spinal stenosis is done in the occurrence of radiological evidence of stenosis on MRI and clinical leg and/or back pain with one or more of the following phenomena: radiculopathy, sensory deficit, motor weakness, reflex pathology or neurogenic claudication.;• Non-responsive to at least 6 months of non-operative treatment prior to study enrollment;
• Fusion indicated for one to six levels in the T10 to S2 region. In case of vertebral osteotomies (PSO or VCR) the osteotomized segment will not be included in the assessment of the fusion rate;
• Willing and able to understand and sign the study specific Patient Informed Consent;
• Skeletally mature between 18 and 80 years of age.

### Exclusion criteria

• Any previous surgical attempt(s) for spinal fusion (revision surgery) of the intended segment(s);
• Previous treatments that compromise fusion surgery like irradiation;
• Previous autologous bone grafting procedures that compromise the quality and amount of iliac crest bone grafting;
• Indication for spinal fusion because of an acute traumatic reason, like a spinal fracture;
• Active spinal and/or systemic infection;
• Spinal metastasis in the area intended for fusion;
• Systemic disease or condition, which would affect the subjects ability to participate in the study requirements or the ability to evaluate the efficacy of the graft (e.g. active malignancy, neuropathy, pregnancy);
• At risk to be non-compliant e.g.: (recently treated for) substance abuse, detainee, likely to immigrate
• Participation in clinical trials evaluating investigational devices, pharmaceuticals or biologics within 3 months of enrollment in this study;
• Female patients who intend to be pregnant within 1.5 year of enrollment in the study;
• Body mass index (BMI) larger than 36 (morbidly obese);
• Being expected to require additional surgery to the same spinal region within the next 6 months;
• Current or recent (<1yr) corticosteroid use equivalent to prednisone >=5mg/day, prescribed for more than 6 weeks.

## Study design

## Design

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Completed |
| Start date (anticipated): | 10-09-2018 |
| Enrollment: | 100 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Generic name: | bone graft substitute |
| Registration: | Yes - CE intended use |

# Ethics review

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| Approved WMO Date: | 30-05-2018 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO Date: | 17-05-2019 |
| Application type: | Amendment |
| Review commission: | METC NedMec |

# 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 | NL64652.041.18 |