A Randomized Controlled Trial of AttraX® Putty vs. Autograft in Instrumented Posterolateral Spinal Fusions

Published: 25-09-2013
Last updated: 24-04-2024

The primary objective of this study is to demonstrate the non-inferiority of AttraX® Putty as a bone graft substitute for autograft in instrumented posterolateral fusion of the thoracolumbar spine, in terms of efficacy and safety.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON44955

Source
ToetsingOnline

Brief title
AxA 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: NuVasive Inc.,NuVasive Inc. (restricted

research grant)

Intervention

Keyword: Bone graft, Ceramic, RCT, Spinal fusion

Outcome measures

Primary outcome

The primary outcomes of this study are the posterior spinal fusion rate after one year (based on CT-scans), and the complication rate and potential relation of (serious) adverse events with AttraX® Putty.

Secondary outcome

Secondary outcomes are the resorption characteristics during the first year, volume of bridging bone mass after one year, evaluation of iliac crest pain, correlation of the posterior fusion rate to the presence of interbody fusion after one year and the posterior spinal fusion rate after two years.

Study description

Background summary

Spinal fusion, a surgical procedure frequently used for many spinal conditions requiring stabilization of the vertebral column, is currently performed by using large amounts of autologous bone graft or autograft. A substitute for this patient own bone would eliminate the graft harvesting morbidity that is currently one of the main disadvantages. Recently, a promising synthetic graft substitute has been developed that has shown favorable results in pre-clinical studies. This product is AttraX® Putty (CE-557130), a bioresorbable tricalcium phosphate (TCP), mixed with a fast resorbing polymer carrier to improve surgical handling.

Study objective

The primary objective of this study is to demonstrate the non-inferiority of AttraX® Putty as a bone graft substitute for autograft in instrumented

posterolateral fusion of the thoracolumbar spine, in terms of efficacy and safety.

Study design

This study is designed as a patient and observer blinded, controlled, randomized, multi-center clinical trial with intra-patient comparisons. This means that each patient is it owns control.

Intervention

According to a randomization scheme, one side of the spine will be grafted with the synthetic ceramic material AttraX® Putty instead of bone harvest from the iliac crest which is currently the gold standard. 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 standard care. Additional procedures for this study include the completion of short patient reported outcome measurements at each regular visit to the clinic and a CT-scan after two years in a subset of the patients. In addition, extra DEXA-scans will be made of 32 patients at each regular follow-up visit. Based on pre-clinical investigations, the risk for inferior performance of AttraX® Putty 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 bone graft morbidity, since only half of the required bone graft will be harvested from the iliac crest.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX

NL

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 or without additional posteriorly inserted interbody devices (PLIF, TLIF), because of (1) deformity, (2) structural instability and/or (3) expected or potential instability, for example as a result of decompression for spinal stenosis or benign lesions;
1. Deformity is defined as a scoliosis in the coronal plane of >20° and/or a sagittal balance disturbance according the SRS classification on standardized standing full spine radiographs;
2. Preoperative instability is defined as >2mm translation 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 or more levels in the T10 to S1/ilium region;
* 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);
* 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 a traumatic reason, like a spinal fracture or traumatic instability;
* 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);
* 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 the study;
* Female patients who intend to be pregnant within 1.5 year of enrollment in the study;
* Body mass index (BMI) larger than 35 (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

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-10-2013
Enrollment:	104
Type:	Actual

Medical products/devices used

Generic name:	Bone graft substitute
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-09-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	30-12-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	06-03-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-05-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-05-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-04-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL44095.041.13