Prospective Hounsfield Unit measurements of intercorporal bone grafts remodelling towards spinal fusion.

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This study has three specific objectives:1) to explore how the participants* intercorporal bone grafts HU develop over time in the first two years after fusion surgery.2) to explore the interobserver reliability of the HU measurements.3) to explore...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational non invasive

Summary

ID

NL-OMON51679

Source
ToetsingOnline

Brief title
Intercorporal Bone Graft Measurement Study

Condition

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

Synonym
Displacement of vertebra in the spine, spondylolisthesis

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: St. Elisabeth's Stichting Arnhem

Intervention

Keyword: Bonegraft remodelling, Hounsfield Units, Interbody fusion, Lumbar spondylodesis

Outcome measures

Primary outcome

The main outcome of interest will be the participants* individual and group (mean, SD) Hounsfield Unit values of their intercorporal bone graft(s) as calculated from their (four) CT-scans. We will use the standardized HU measurement protocol developed during a feasibility study. The HU will be assessed independently by three observers.

Secondary outcome

Secondary outcomes include the Oswestry Low Back Pain Disability Questionnaire (ODI), Research and Development 36 (RAND-36), Visual Analogue Scale (VAS) for back and leg pain and the intercorporal fusion result criteria by Brantigan et al.

Study description

Background summary

Low (lumbar) back pain and concomitant leg pain are common and a major cause of global disability. Lumbar spinal fusion (lumbar spondylodesis) is a surgical procedure is used for many diseases that cause lumbar back pain, and the use of this treatment has increased in recent decades. Lumbar spondylodesis has been shown to reduce pain and improve functional status. With spondylodesis, the intervertebral disc is removed and bone graft is placed between the two vertebrae. Over time, this becomes vital bone, creating a lasting fusion of the two vertebrae. The vertebrae are also fixed with pedicle screws and metal rods to provide immediate stability after surgery.

The success of the fusion is partly determined by the amount, and quality, of bone formed between the two lumbar bodies. Radiological scoring is used to

monitor fusion. One method of quantifying bone formation in instrumented areas is by using Hounsfield Units (HU) measured by Computed Tomography (CT) imaging, where an increase in HU correlates with higher bone density. HU are measured in a specific area (Region of Interest). Clinically, HU measurements are already used to evaluate bone quality, for example prior to spinal surgery.

In the literature, only little is known about quantification of the biological process of bone graft remodelling and the occurrence of fusion between vertebral bodies. Only one prior study has used HU to evaluate the changing bone density of bone graft after lumbar fusion, but they did not use the same subjects for HU measurements at different time points in the follow-up.

By quantifying the bone density of individual patients' bone grafts at different times during follow-up, clinicians can evaluate the quality and progression of bone formation. In addition, it can help elucidate the biological process of bone graft remodelling. This will help us understand how long it may take for the bone graft to finish remodelling. In addition, and perhaps more importantly - it may help to predict the failure of fusion with early recognition of symptomatic pseudo-arthrosis. In doing so, we will compare the trend in HU with the most commonly used fusion scoring criteria and administer clinically related questionnaires.

Prior to this study, we have already conducted a retrospective pilot study using patients with consecutive 1- and 2-year postoperative CT scans. In this study, we developed a protocol for measuring bone graft on two follow-up CT scans and evaluated whether this methodology could be reliably performed by a single observer. The methodology was validated in this study. The results showed that in 78% of the patients the bone graft was still remodelling to a higher bone density, meaning that better quality bone is still being formed.

Study objective

This study has three specific objectives:
1) to explore how the participants* intercorporal bone grafts HU develop over time in the first two years after fusion surgery.
2) to explore the interobserver reliability of the HU measurements.
3) to explore if the participants* upward, downward or no trend in HU values correlate with trends of scores on a commonly used interbody fusion classification and the degree of back and/or leg pain.

Study design

This is a single-center prospective exploratory study. During this study a convenience sample of participants, who have undergone lumbar spinal fusion in Rijnstate Hospital and who have agreed to participate in the study, will have (four) CT-scans of the lumbar spine taken in the first week after surgery, and

again after 6, 12 and 24 months.

Study burden and risks

Participants will be asked to undergo four low-dose CT-scans of the instrumented segment over a two-year period. During standard care, fusion patients undergo three conventional lumbar radiographs (after 6 weeks, 3 months, and 1 year) and one CT-scan (after 1 year). In our hospital, the effective median exposure doses of standard lumbar radiographs and CT-scans are 0,2 mSv and 2,4 mSv, respectively. This exposes each patient to a total radiation dose of (3 x 0,2 + 1 x 2,4) = 3,0 mSv in one year. Without taking any additional measures, four *study* CT-scans would expose the participants to a total radiation dose of (4 x 2,4 =) 9,6 mSv in two years. To mitigate this increased radiation risk, and to lower the participants* radiation exposure during the study, we will:
1) focus the CT-scan of the lumbar region on the instrumented segment only (2 instead of the regular 6-7 vertebral bodies). This measure will reduce the radiation dose by up to 60% (approximately 1.4 mSv) per CT-scan, and hence reduce the overall CT-based radiation dose by (4 x 1,4 =) 5,6 mSv.
2) replace the conventional lumbar radiographs by the study CT-scans. This measure will prevent participants from also receiving a standard radiation dose of 3 x 0,2 = 0,6 mSv mSv from the radiographs.

By taking the above two measures, the patient*s effective dose of radiation exposure during the study will be around 7,2 mSV compared to the 3,0 mSv during regular care. As such, compared to regular care, participants will be exposed to higher dose of radiation by participating in this study. It is of note that we will only recruit patients over the age of 45. In this age group the lifetime risk of radiation induced carcinogenesis is known to decline rapidly.

Considering the above, and applying the risk classification as proposed by the Dutch Commission of Radiation Dosimetry we estimate that the additional radiation risk is moderate (*matig risico*). We disscused the above with the clincal physicist and we believe that the benefits, of gaining insight in how patients* intercorporal bone grafts HU develop over time in the first two years after fusion surgery, and if the patients* upward, downward or no trend in HU values correlate with trends of scores on a commonly used interbody fusion classification and the degree of back and leg pain, outweighs this risk.

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

Patients are only eligible for participation if they i) were non-responsive to non-operative treatment in the six months prior to study enrolment, ii) have fusion indicated for only one segment in the L1 to S1/ilium region and iii) are between the age of 45 and 80.

Exclusion criteria

Patients will be excluded from participation if they i) will receive revision spine surgery, ii) do not want to provide informed consent or when iii) pregnant or expecting to be pregnant within in the next two years.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-12-2022
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Computed Tomography scanner: IQon Spectral CT powered by iPatient;software v4.7.7.43220 (31 may 2021
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	22-09-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL81678.091.22