A prospective patient registry for bonegraft substitutes in spinal fusion

Published: 21-06-2011
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To identify the patient profile for Actifuse and for other grafting products used to achieve bone fusion.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Connective tissue disorders (excl congenital)
Study type	Observational invasive

Summary

ID

NL-OMON36368

Source
ToetsingOnline

Brief title
APPROACH-001-EU

Condition

- Connective tissue disorders (excl congenital)
- Bone and joint therapeutic procedures

Synonym
Patients undergoing a spinal fusion surgery, spinal surgery

Research involving
Human

Sponsors and support

Primary sponsor: ApaTech Limited
Source(s) of monetary or material Support: Industry

Intervention

Keyword: Bone fusion, Bone graft substitutes, Spinal fusion

Outcome measures

Primary outcome

A patient profile for Actifuse and for other grafting products used to achieve

bone fusion.

Secondary outcome

Overall successrate of the individual effectiveness endpoints, including

improvement in outcomescales, neurologic improvement and radiographic fusion

success.

Study description

Background summary

This observational study will assess the use of commercially available bone graft substitutes in spine fusion, as well as autograft according to the investigators local practice.

Study objective

To identify the patient profile for Actifuse and for other grafting products used to achieve bone fusion.

Study design

A prospective patient registry

Study burden and risks

Two extra visits to the outpatient department (12 and 24 months) and an extra CT scan and 2 extra X-rays during those visits.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

requiring spinal fusion surgery
failed conservative treatment
>18 year

Exclusion criteria

Systemic infection or infection op the surgical site
Poor general health
Substance abuse
Pregnancy

participation in another trial

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-07-2011
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	23-06-2011
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL34651.075.10