ISRCTN38726728 https://doi.org/10.1186/ISRCTN38726728

AttraX® Putty in spinal fusion

Submission date
28/11/2011

Recruitment status
No longer recruiting

Registration date
15/12/2011

Overall study status
Stopped

Last Edited
26/03/2018

Condition category
Musculoskeletal Diseases

- [ ] Prospectively registered
- [ ] Protocol
- [ ] Statistical analysis plan
- [ ] Results
- [ ] Individual participant data
- [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A bone graft is a material that is placed between your spine bones (vertebrae) to help them fuse together. A bone graft may come from a piece of your own bone (autograft), a donor graft (allograft), or a graft substitute (synthetic or man-made material). AttraX Putty is a synthetic replacement for bone that may be used in spinal fusions without needing autograft. AttraX Putty has a combination of materials that help with bone growth. The aim of this study is to find out how effective AttraX Putty is as a bone graft substitute compared with the other options that are currently available for spinal fusions. We are interested in finding out whether there are differences in spine fusion rates and pain levels for the different types of bone graft.

Who can participate?
Patients aged 18-70 undergoing spinal fusion surgery.

What does the study involve?
Before surgery the participants undergo tests to document their health and pain. Participants attend follow-up visits to see their surgeon 2 weeks, 3 months, 6 months, 12 months, and 24 months after surgery. If the spine is not considered fused by the 12-month visit then a second CT scan is required at 24 months . All follow-up visits are scheduled at the same intervals as the standard follow-up schedule and take about 15 minutes longer than a regular outpatient visit (for the completion of questionnaires).

What are the possible benefits and risks of participating?
Participants will not incur any additional costs beyond those normally associated with this type of surgery and follow-up visits. Participants will not be compensated directly for their participation in the study. Participants will have one or more scans which use radiation.

Where is the study run from?
NuVasive, Inc. (USA).

When is the study starting and how long is it expected to run for?
December 2011 to December 2013.

Who is funding the study?
NuVasive, Inc. (USA).

Who is the main contact?
Kelli Howell

Contact information

Type(s)
Scientific

Contact name
Ms Kelli Howell

Contact details
7475 Lusk Blvd
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Additional identifiers

Protocol serial number
NUVA.AX1101

Study information

Scientific Title
AttraX® Putty in spinal interbody fusion: Evaluation of radiographic and clinical outcomes

Acronym
NUVA.AX1101

Study objectives
1. To evaluate the fusion rate following the use of AttraX®Putty in spinal fusion procedures performed at one or two contiguous level(s) of the cervical and lumbar spine.
2. To evaluate the complication rate associated with the use of AttraX®Putty compared to published and/or retrospective data for autograft, allograft, synthetics, bone morphogenic protein (BMP), or other graft alternatives.
3. To evaluate and identify any relationships between clinical outcomes (pain and function) and radiographic outcomes (fusion rate)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective non-randomized multi-arm observational study

Primary study design

Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Degenerative conditions of the lumbar and cervical spine

Interventions
1. Study Arm: Anterior Approach Cervical Interbody Fusion(ACDF)
ACDF with CoRoent® Small Contoured or Small Lordotic Plus (SLP) and AttraX® Putty in the interbody space, and with NuVasive Helix ACPTM
2. Study Arm: Anterior Approach Lumbar Interbody Fusion
eXtreme Lateral Interbody Fusion (XLIF) using CoRoent XL or Anterior Lateral Interbody Fusion (ALIF) using BrigadeTM or XLR implant(s) and AttraX® Putty in the interbody space, and with bilateral posterior stabilization by Armada® or SpheRx® pedicle screw system.
3. Study Arm: Posterior Approach Lumbar Interbody Fusion
Bilateral or unilateral Posterior Lumbar Interbody Fusion (PLIF) or Transforaminal Lumbar Interbody Fusion (TLIF) using CoRoent Large or Large Oblique (LO) implant(s) (respectively) and AttraX® Putty in the interbody space, and with bilateral posterior stabilization by Armada or SpheRx pedicle screw system.
All postoperative restrictions and rehabilitation of the subject are per the Investigators standard of care.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The radiographic fusion rates at 12 months and 24 months

Key secondary outcome(s))
1. The complication rate attributable to the use of AttraX® Putty
2. The evaluation of angular displacement on flexion / extension films at the 6-, 12-, and 24-month follow-up visits
3. The evaluation of bridging bone on computerised tomography (CT) at 12- and 24-month (as required) follow-up visits
4. Preservation of interverterbal disc height over time
5. The change in American Spinal Injury Association (ASIA) score from baseline at each follow-up visit
6. The change in subject self-reported pain scores Visual Analogue Scale (VAS) from baseline at each follow-up visit
7. The change in Neck Disability Index (NDI) or Oswestry Disability Index (ODI) scores from baseline at each follow-up visit
8. The change in SF-36 scores from baseline at each follow-up visit
9. Patient satisfaction at each follow-up visit
10. The number of subjects returning to employment and the mean time of return to employment (as applicable)

Completion date
01/12/2013

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Persistent arm pain unresponsive to conservative treatment for at least 6 weeks or persistent back and/or leg pain unresponsive to conservative treatment for at least 6 months, unless surgical treatment is clinically indicated sooner
2. Indicated for anterior cervical discectomy and fusion (ACDF), anterior lumbar interbody fusion (ALIF or XLIF), or posterior lumbar interbody fusion (PLIF or TLIF) at one or two contiguous motion segments (C3 to T1 in the cervical spine or L1 to S1 in the lumbar spine)
3. Objective evidence of primary diagnosis must be confirmed by appropriate imaging studies
4. 18-70 years of age at the date of written informed consent
5. Able to undergo surgery based on physical exam, medical history and surgeon judgment
6. Expected to survive at least 2 years beyond surgery
7. Willing and able to return for post-treatment exams according to the follow-up called for in the protocol
8. Signed and dated informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Key exclusion criteria
1. Mental or physical condition that would limit the ability to comply with study requirements
2. Previous failed fusion at any spinal level
3. Prior fusion procedure at operative level(s) (i.e. no revision of prior level)
4. Prior instrumented fusion at level(s) adjacent to operative level(s)
5. Systemic or local infection; active or latent
6. Diseases that significantly inhibit bone healing (e.g., osteoporosis, metabolic bone disease)
7. Treatment with pharmaceuticals interfering with calcium metabolism
8. Undergoing chemotherapy or radiation treatment
9. Chronic use of steroids (defined as more than 6 weeks of steroid use within 12 months of surgery, other than episodic use or inhaled corticosteroids)
10. Involvement in active litigation relating to the spine (worker's compensation claim is allowed

if it is not contested)
11. Significant general illness [e.g., human immunodeficiency virus (HIV), active metastatic cancer of any type, uncontrolled diabetes, dialysis dependent renal failure, symptomatic liver disease]
12. Immunocompromised or is being treated with immunosuppressive agents
13. Pregnant, or plans to become pregnant during the study
14. A prisoner
15. Participating in another clinical study that would confound study data

Date of first enrolment
01/12/2011

Date of final enrolment
01/12/2013

Locations

Countries of recruitment
United Kingdom

Germany

United States of America

Study participating centre
NuVasive, Inc.
San Diego
United States of America
92121

Sponsor information

Organisation
NuVasive, Inc. (USA)

ROR
https://ror.org/036dqy506

Funder(s)

Funder type
Industry

Funder Name
NuVasive, Inc. (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration