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Facet joint resurfacing for chronic non-specific low back pain

Submission date
12/02/2019

Recruitment status
No longer recruiting

Registration date
19/03/2019

Overall study status
Completed

Last Edited
09/07/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
One of the potential causes of non-specific chronic low back pain (CLBP) is degenerative disease of the zygapophyseal (facet) joints. Up till now, no treatment aiming at restoring the joint and its functionality is available. Similar to the proven benefits of joint replacement techniques used for restoration of the functionality of the larger joints such as the hip and the knee and the smaller ones such as the joint of the base of the thumb, the idea of replacing the facet joint is appealing. Prostheses have been developed as adjuvant treatment to surgical disc decompression, discectomy and facetectomy. The FENIX Facet resurfacing implant under study offers the advantage that it can be placed without fixation of adjacent vertebrae and can be used for the treatment of degenerative facet joints without other pathology. This study aims to to evaluate the safety of the FENIX Facet resurfacing implant, the feasibility of the surgery, the clinical outcome in terms of pain relief, disability, medication intake and return to work, and the radiological findings in terms of implant location and mobility of the index segment.

Who can participate?
Patients presenting at the investigators' clinics with non-specific CLBP attributable to facet joint degeneration

What does the study involve?
Patients receive a unilateral FENIX implantation, after the baseline information has been obtained. Patients are asked to return at regular intervals (12, 26, 52 and 104 weeks after surgery) for clinical and if required x-ray evaluation. During those follow-up visits the patients fill out questionnaires and to report which medication they use at which dose. All side effects and complications during and after surgery are noted.

What are the possible benefits and risks of participating?
The majority of the patients who received a FENIX implant during a pilot study and during normal clinical practice experienced significant pain relief and improved mobility. This effect is also expected in patients participating in this study. As with any surgery the anesthetic procedure may consist a risk factor for certain patients. The medical imaging and especially the plain X-rays expose the patient to ionizing radiation that may be harmful for the unborn fetus. The dose used during this study is not of a level to form a risk for cancer. There may be wear of

the implant causing metal particles to be able to accumulate in the surrounding tissues. The chances for this to happen are limited.

Where is the study run from?
The study will be conducted in the department of neurosurgery of the AZ Nikolaas, Sint-Niklaas, Belgium

When is the study starting and how long is it expected to run for?
August 2016 to January 2023

Who is funding this study?
This is an investigator-initiated study on an intervention that is normal practice. The materials and the intervention are reimbursed. The extra administration costs are covered by the PI (E. Van de Kelft).

Who is the main contact?
Prof. dr. Erik Van de Kelft
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AZ Nikolaas-FENIX 2017/02

Study information

Scientific Title
Investigator-initiated, single-center prospective study on the clinical and radiological outcome after FENIX ® Facet Resurfacing Implant insertion in patients with chronic non-specific low back pain

Study objectives
Chronic low back pain may be attributed to facet joint degeneration. Conservative treatment and interventional pain management techniques are symptomatic. Fusion surgery decompresses the joint complex at the depense of motion. In analogy with joint replacement or resurfacing of the hip, knee and smaller hand joints a resurfacing of facet joint can provide pain relief and restore functionality. This study aims at assessing the clinical and radiological outcome of FENIX facet joint resurfacing.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 16/11/2017, The ethical committee of AZ Nikolaas (Moerlandstraat, 1, Sint-Niklaas, 9100 , Belgium; +32 (0)3 760 25 93; Dominique.capens@aznikolaas.be), ref: 2017-11/EC 17026

2. Approved 09/12/2021, Commissie voor Medische Ethiek, AZ Nikolaas (Moerlandstraat, 1, Sint-Niklaas, 9100, Belgium; +32 3 760 60 60; info@vitaz.be), ref: EC21046

Study design
Prospective single-center study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Chronic low back pain attributable to degenerative facet joints

Interventions
Thirty consecutive patients presenting at the investigators' clinics with non-specific CLBP attributable to facet joint degeneration will be selected for FENIX implantation. After having obtained the patients' written informed consent they will be included into the study.
The baseline data to be assembled consist of:
1. The clinical and neurological examination,

2. The patient’s assessment of the pain intensity and frequency and his/her functionality.
3. The consumption of analgesic medication
4. Radiographic (Functional X-ray and MRI) documentation

Patients will be asked to return at regular intervals (12, 26, 52 and 104 weeks post-surgery) for clinical and if required radiological evaluation. During those follow-up visits the patients will be asked to fill out evaluation questionnaires and to report which medication he/she uses at which dose. All side effects and complications during and post-surgery will be noted.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
FENIX facet joint resurfacing device

Primary outcome measure
Pain measured by VAS and functionality measured by the Oswestry Disability Index and radiological stability

Secondary outcome measures
1. Clinical examination consisting of: paravertebral tenderness, pain radiation pattern, absence of exacerbation with coughing, relief with recumbency, pain not worsened by forward flexion or rising from forward flexion, and pain not exacerbated by hyperextension or extension-rotation. The neurological examination should exclude radicular pain (weakness in the legs, positive Lasègue test). This is only done at intake
2. Patient’s assessment of the pain intensity using a 10-cm visual analogue scale at intake, 12, 26, 52 and 104 weeks
3. Pain frequency measured with a 5-point Likert scale (1 continuously pain, 2 pain most of the time, 3 regularly pain, 4 seldom pain, 5 no pain or only flare-up) at intake, 12, 26, 52 and 104 weeks
4. Functionality measured using the Oswestry Disability Questionnaire at intake, 12, 26, 52 and 104 weeks
5. The consumption of analgesic medication recorded at each visit, analysis will be done according to the Medication Quantification Scale at intake, 12, 26, 52 and 104 weeks
6. Radiographic examination using MRI and SPECT-CT at baseline
7. Flexion extension X-rays and AP and lateral X-rays performed at intake and at 26, 52 and 104 weeks
8. Side effects and complications noted during and post-surgery. These parameters are normally included in the patients’ file and are also included in the study record card. These involve blood loss, potentially infections.
9. Surgical parameters (duration of the surgery, blood loss, need for additional blood administration, type and size of the implant) noted immediately after surgery
10. Duration of incapacity to work. The patient is questioned regarding his work status at intake. If in incapacity to work the duration of this incapacity is questioned. At each of the follow-up visits 12, 26, 52 and 104 weeks the work status is controlled and the duration of incapacity to work is noted.
11. Patient social activities. The patient is questioned about social activities at intake and 12, 26, 52 and 104 weeks

Overall study start date
24/08/2016

Completion date
31/01/2023

Eligibility

Key inclusion criteria
1. Subject has a history of non-specific chronic low back pain (CLBP) for more than 6 months suggestive for “facet joint syndrome” (See clinical diagnosis in Attachment 1)
2. Subject age is between 20 and 70 years and is skeletally mature
3. Failed conservative treatment for 3 months, including rehabilitation treatment, pharmacological and minimal interventional treatment.
4. Positive diagnostic nerve block (See Section 10.3)
5. Condition involves at least one lumbar spine level between contiguous levels L1 to S1.
6. Back pain intensity of at least 5 on a scale of 10 (VAS).
7. Oswestry score > 40 (based on 100-point scale)
8. Pain frequency of at least 3 on a 5-point scale
9. Radiology features suggestive for facet joint pathology. (See Section 10.2 for definitions) That is, the patient must have radiographic evidence of facet joint degeneration on Magnetic Resonance Imaging, classified as 1 or 2 on the Weishaupt scale and the SPECT-CT must show a hotspot level 2 at the facet joint, suspected to be the cause of low back pain

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
30

Total final enrolment
10

Key exclusion criteria
1. Subject has any isthmic spondylolisthesis or degenerative spondylolisthesis >3mm detected on plain X-rays
2. Subject has had prior spine surgery at the index level
3. Subject has disc herniation that is not contained (3 or 4 on the Milette scale)

4. Subject has central spinal canal stenosis
5. Subject has Cauda Equina Syndrome
6. Subject's facet joints are absent or fractured.
7. Subject is morbidly obese, having a Body Mass Index (BMI) of 35 or greater
8. Kidney disease (serum creatinine >235 µmol)
9. Subject has an active systemic infection or at the operative site
10. Subject has a spinal tumor
11. Subject has a known Chrome-Cobalt allergy.
12. Subject is pregnant or plans to become pregnant during the study
13. Subject is at high risk for evolution to chronicity (StarT back screening tool)

Date of first enrolment
01/12/2018

Date of final enrolment
01/12/2019

Locations

Countries of recruitment
Belgium

Study participating centre
AZ Nikolaas, Dept of Neurosurgery
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Sponsor information

Organisation
AZ Nikolaas

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Sponsor type

Hospital/treatment centre

Website
www.neuro-chirurgie.org

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The study protocol is published on the website: www.neuro-chirurgie.org under the heading “clinical trials” and next to “FENIX facet study protocol” this is a password-protected part of the site: the password can be requested from Dr Van de Kelft (erik.vande kelft@aznikolaas.be).

The study report will be made available to the ethical committee of AZ Nikolaas, 3 months after the last assessment of the last included patient.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The data will be stored as an Excel file on the website www.neuro-chirurgie.org under the heading “clinical trials” and next to “FENIX facet study participant date”. This is a password-protected part of the site: the password can be requested from Dr Van de Kelft (erik.vande kelft@aznikolaas.be).

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2	18/02/2018	17/08/2022	No	No