A Randomized, Double-blind, Placebo-controlled, Multicenter Efficacy Study of the Gelstix* Device to treat Chronic Discogenic Low Back

Published: 13-04-2017
Last updated: 16-04-2024

The primary objective of this study is to quantify the reduction in lumbar pain in a GelStix* treatment group compared with a control group receiving a saline solution injection as placebo.The secondary objectives are to assess: 1. the impact of...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nervous system, skull and spine therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON46154

Source
ToetsingOnline

Brief title
GelStix Study

Condition

- Nervous system, skull and spine therapeutic procedures

Synonym
discogenic pain, lumbar degenerative disc disease

Research involving
Human

Sponsors and support

Primary sponsor: EOC Lugano

Source(s) of monetary or material Support: from Sponsor;Lugano,Replication Medical, Inc

Intervention

Keyword: Chronic Discogenic Low Back Pain, Gelstix

Outcome measures

Primary outcome

Lumbar pain intensity measured on Numeric Rating Scale at baseline and 6 months

post-treatment

Secondary outcome

1. Changes in disability: Owestry Disability Index,

2. Changes in health related quality of life: EuroQualityOfLife-5 dimensions

questionnaire,

3. Reliance on medication to relieve pain: type and dose of analgesics

4. Device-related adverse events assessed up to one year

Study description

Background summary

Degenerative Disc Disease (DDD) is one of the most common spinal pathologies, affecting up to 10-15 % of adults. The degeneration is associated with diminished water-binding capabilities of the nucleus pulpous leading to disc dehydration, volume reduction, changes in cellular activity, biomechanical changes and painful symptoms. Patients are initially treated with non-surgical pain-management techniques, such as anti-inflammatory medications and physical therapy, but these therapies often provide only temporary relief. When non-surgical intervention fails, fusion or total disc arthroplasty are often prescribed, both of which are highly invasive surgeries with significant associated morbidity. Clearly, a meaningful solution for the treatment gap existing between conservative care and invasive surgical intervention is needed. The purpose of this study is to evaluate the efficacy of treatment with the GelStix* device in a patient population that had no benefit from conservative

care.

Study objective

The primary objective of this study is to quantify the reduction in lumbar pain in a GelStix* treatment group compared with a control group receiving a saline solution injection as placebo.
The secondary objectives are to assess:
1. the impact of treatment with GelStix* on disability compared with the control group
2. the impact of treatment with GelStix* on health related quality of life compared with the control group
3. the impact of treatment with GelStix* on reliance on medication to relieve the pain compared with the control group
4. the acute and long-term safety of the GelStix* device and implant system

Study design

Double-blind, prospective, randomized, placebo-controlled, outcome study

Intervention

Treatment group: intradiscale implantation of the GelStix* Nucleus Augmentation Device (STX-1835S GelStix*, Replication Medical, Inc. - Cranbury, NJ, USA).

Placebo group: intradiscal injection with saline (1 mL NaCl 0.9%).

Study burden and risks

DDD is one of the most common spinal pathologies, impacting up to 10-15 % of adults. Whereas non-invasive therapies often provide only temporary relief, patients are often recommended for fusion or total disc arthroplasty, both of which are highly invasive surgeries with significant associated morbidity. Clearly, a meaningful solution for the treatment gap existing between conservative care and invasive surgical intervention is needed.
As with a conventional surgical procedure and pain management treatments, there is a possibility of infection, bleeding, nerve damage and/or limited motion as a result of the procedure. There is also a chance that the nucleus augmentation implant will not resolve difficulties that the patient has with regard to pain and functioning. Risks associated with use of nuclear augmentation may include displacement leading to nerve or spinal cord compression and injury. If the surgeon encounters great difficulty in completing the nuclear augmentation, he may choose not to proceed with implantation. Other risks include, annular tear, extrusion into the epidural space. In order to minimize the likelihood of complications, only physicians trained in interventional or diagnostic procedures such as discography will perform the nuclear augmentation procedure

on a patient.
Literature on the GelStix* support the implementation of the study. There has been only a single complication and it was deemed by the investigators to be due to a surgically misplaced implant. Clinical risks of expulsion and endplate remodeling have proven to be low-probability to non-existent. On the other hand, the published data support the clinical benefit in treatment of discogenic pain. Most patients experienced significant and sustained pain and disability reductions assessed by the validated Visual Analog Scale and Oswestry Disability Index.

Contacts

Public
EOC Lugano

Via Pietro Capelli 1
Viganello 6962
CH
Scientific
EOC Lugano

Via Pietro Capelli 1
Viganello 6962
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age between 18-66 years.

- One or two levels of lumbar degenerative disc disease on magnetic resonance imaging (MRI) scan with Pfirrmann grade 2, 3 or 4.
- Positive discography
- Predominant persistent, nociceptive low back pain that worsens with axial loading and improves with recumbence of at least 12 weeks duration.
- Failure to have symptoms resolved or reduced following at least 12 weeks conservative care (pain medication and/or physical therapy).
- Annulus must be competent as determined by lumbar discography
- Negative medial branches block results.
- Patients presenting with a baseline level scores evaluated by NRS of at least 5/10.
- Patients who are legally competent and able to understand the nature, scope and aim of the clinical investigation

Exclusion criteria

- Radiculopathy caused by nerve root compression.
- Frank herniations, extruded or sequestered fragments, bulge/protrusions >3mm at any lumbar disc level.
- Greater than grade 4 annular tear (Modified Dallas Grading) at any lumbar disc level.
- Severe symptomatic central, foraminal or lateral recess stenosis, spondylolysis, spondylolisthesis, acute fractures, or ankylosing spondylitis at any lumbar disc level.
- Coagulopathy or oral anticoagulant therapy (except low-dose acetylsalicylic acid) in conditions that do not allow for a temporary discontinuation.
- Active infection, systemic or localized; any disease process or condition that may make the effect of the treatment difficult to evaluate (e.g. cancer, substance abuse, etc.)
- Previous surgery at any lumbar disc level.
- Disc height less than 5mm at the symptomatic level, or less than 50% of the highest lumbar disc
- Presence of Schmorls nodes at the implanted level.
- Females of childbearing age that are known to be pregnant or wishing to be pregnant during the study.
- Psychological disorders or factors that may impact upon treatment outcomes or compliance (e.g. severe depressions).
- Failure to understand informed consent or participation in any other clinical study.
- BMI (Body Mass Index (kg/m2) of >= 35

Study design

Design

Study phase: 3

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2017
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	GelStix Nucleus Augmentation Device
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-04-2017
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
ClinicalTrials.gov	NCT02763956
CCMO	NL57568.091.16