A MULTI-CENTER, POST MARKETING SURVEILLANCE STUDYTO MONITOR THE SAFETY AND PERFORMANCEOF THE BARRICAID® ARD IN THE TREATMENT OF BACK ANDRADICULAR PAIN CAUSED BY PRIMARY LUMBAR DISCHERNIATION

Published: 04-11-2008
Last updated: 06-05-2024

Safety and performance will be based on a comparison of overall success rates of the Barricaid ARDand either a concurrent group (nonrandomized) of control patients treated by conventional surgicalmethods (e.g., noninstrumented discectomy) at select...

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

Summary

ID

NL-OMON32568

Source
ToetsingOnline

Brief title
BARRICAID

Condition

- Nervous system, skull and spine therapeutic procedures

Synonym
hernia, lumbal disc herniation

Research involving

Human

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis
Source(s) of monetary or material Support: Bedrijf,Intrinsic Therapeutics Inc

Intervention

Keyword: Barricaid, lumbar disc, post marketing

Outcome measures

Primary outcome

NVT

Secondary outcome

NVT

Study description

Background summary

Lumbar discectomy has become the most common spinal procedure in the US, with nearly 300,000procedures performed each year because of the epidemic problem of low-back pain, which leads to15 million physician visits per year and has created a tremendous financial burden on societyexceeding $50 billion annually.1,2,3,4 Low-back pain causes nearly 80% of injured workers to miss atleast 8 weeks of work following a back injury.5 In persons younger than 45 years old, low-back pain isthe most frequent cause of activity limitation.6 Although only 4% of patients with low-back pain havean acute disc herniation4,7, a disproportionate 30% of US annual costs for the treatment of low-backpain are spent on this relatively small percentage of patients.8The incidence of lumbar disc herniation peaks in patients between 24 and 45 years of age with theincidence leading to surgery occurring most often in patients in the 30- to 39-year-old range. 9 A malepredominance in the incidence of lumbar disc surgery ranges from 1.3:1 to 2:1 because discs in menundergo higher mechanical stress as well as inadequate nutrition due to longer nutrient diffusionpathways.10,11 Other risk factors for herniated lumbar discs include smoking, presence of narrowerlumbar vertebral canal, sedentary occupations, prolonged motor vehicle driving, and operatingvibrating machinery.12,13 Most surgeons initially manage patients with low-back pain and radicularsymptoms

with a trial of analgesic medications and physical therapy for several weeks before

Study objective

Safety and performance will be based on a comparison of overall success rates of the Barricaid ARDand either a concurrent group (nonrandomized) of control patients treated by conventional surgicalmethods (e.g., noninstrumented discectomy) at select European sites or the published clinicalliterature on the same patient population. Overall clinical success is based on a 15% improvement inOswestry and a two point (2 point on a 10 point scale) improvement in VAS Leg (combined) scores.Overall radiographic success requires maintenance of average disc height (75% or greater ofpreoperative disc height). Safety will be judged clinically using standard neurological assessmentsand clinically symptomatic reherniation. A successful patient will not experience a loss ofneurological function (at the index level) nor experiences reherniation at the original defect site. Allreoperations that involve the removal/ repositioning of the Barricaid ARD or the addition ofsupplemental hardware at the index level will cause the patient to be classified as a failure. Inaddition, safety will be documented based on the type and rate of occurrence of adverse eventsoccurring during the study. The Barricaid ARD will be determined to be safe and performing asintended if the Barricaid ARD rates of overall success are equivalent or better than the controlpopulation.

Study design

This clinical trial is a prospective, multicentre, historical controled study to evaluate the safety and performance of the Barricaid ARD by treatment of lumbal disc herniation

Intervention

NVT

Study burden and risks

The risks of the BARRICAID* surgery combined with the conventional treatment are: a) infection of wounddrainage; b)return of the herniation; c)effects on the central nerve system;d) same symptoms as before the surgery; e) migration of the device in of out the lumbal disc;f)death as complication of the surgery or anesthesia

Contacts

Public
Canisius Wilhelmina Ziekenhuis

Weg door Jonkerbos 100
6532 SZ Nijmegen
NL
Scientific
Canisius Wilhelmina Ziekenhuis

Weg door Jonkerbos 100
6532 SZ Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Any subject meeting all of the following criteria will be considered acceptable for inclusion in this trial.1. Age 18 to 75 years old (male or female).2. Patients with posterior or posterolateral disc herniations at one or two levels between L1 andS1 with radiographic confirmation of neural compression using CT and/or MRI.3. At least six (6) weeks of failed, conservative treatment prior to surgery, including physicaltherapy, use of anti-inflammatory medications at maximum specified dosage and/oradministration of epidural/facet injections.;4. Minimum posterior disc height of 3mm at the index level(s).5. Lower back pain and/or sciatica with or without spinal claudication.6. Oswestry Questionnaire score of at least 40/100 at baseline.7. VAS leg pain of at least 40/100 at baseline.8. Psychosocially, mentally and physically able to fully comply with the clinical protocol and willingto adhere to follow-up schedule and requirements.

Exclusion criteria

3.1.2 EXCLUSION CRITERIAAny subject meeting any one of the following criteria will be excluded from enrollment into the trial:1. Spondylolisthesis Grade II or higher2. Subject requires uni or bilateral facetectomy to treat leg/back pain3. Subject has back or non-radicular leg pain of unknown etiology.4. Prior fusion (with or without instrumentation), motion preservation, facetectomy or IDETsurgery at the index lumbar vertebral level5. Subject*s requiring a spine DEXA (i.e., patients with SCORE of = 6) with a T Score lessthan -2.0 at the index level.6. Subject has clinically compromised vertebral bodies at the index level(s) due to any traumatic,neoplastic, metabolic, or infectious pathology.7. Subject has sustained pathologic fractures of the vertebra or multiple fractures of the vertebraor hip.8. Subject has scoliosis of greater than ten (10) degrees (both angular and rotational).9. Any metabolic disease bone disease that has not been stabilized for at least three months

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-04-2009
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Barricaid ARD
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-11-2008
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	NL23971.091.08