

# A MULTI-CENTER, POST MARKETING SURVEILLANCE STUDY TO MONITOR THE SAFETY AND PERFORMANCE OF THE BARRICAID® ARD IN THE TREATMENT OF BACK AND RADICULAR PAIN CAUSED BY PRIMARY LUMBAR DISC HERNIATION

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Nervous system, skull and spine therapeutic procedures
<b>Study type</b>	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

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4-05-2025

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 300,000 procedures performed each year because of the epidemic problem of low-back pain, which leads to 15 million physician visits per year and has created a tremendous financial burden on society exceeding \$50 billion annually.<sup>1,2,3,4</sup> Low-back pain causes nearly 80% of injured workers to miss at least 8 weeks of work following a back injury.<sup>5</sup> In persons younger than 45 years old, low-back pain is the most frequent cause of activity limitation.<sup>6</sup> Although only 4% of patients with low-back pain have an acute disc herniation<sup>4,7</sup>, a disproportionate 30% of US annual costs for the treatment of low-back pain are spent on this relatively small percentage of patients.<sup>8</sup> The incidence of lumbar disc herniation peaks in patients between 24 and 45 years of age with the incidence leading to surgery occurring most often in patients in the 30- to 39-year-old range.<sup>9</sup> A male predominance in the incidence of lumbar disc surgery ranges from 1.3:1 to 2:1 because discs in men undergo higher mechanical stress as well as inadequate nutrition due to longer nutrient diffusion pathways.<sup>10,11</sup> Other risk factors for herniated lumbar discs include smoking, presence of narrower lumbar vertebral canal, sedentary occupations, prolonged motor vehicle driving, and operating vibrating machinery.<sup>12,13</sup> Most surgeons initially manage patients with low-back pain and radicular symptoms

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 ARD and either a concurrent group (nonrandomized) of control patients treated by conventional surgical methods (e.g., noninstrumented discectomy) at select European sites or the published clinical literature on the same patient population. Overall clinical success is based on a 15% improvement in Oswestry 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 of preoperative disc height). Safety will be judged clinically using standard neurological assessments and clinically symptomatic reherniation. A successful patient will not experience a loss of neurological function (at the index level) nor experiences reherniation at the original defect site. All reoperations that involve the removal/ repositioning of the Barricaid ARD or the addition of supplemental hardware at the index level will cause the patient to be classified as a failure. In addition, safety will be documented based on the type and rate of occurrence of adverse events occurring during the study. The Barricaid ARD will be determined to be safe and performing as intended if the Barricaid ARD rates of overall success are equivalent or better than the control population.

## **Study design**

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

## **Intervention**

NVT

## **Study burden and risks**

The risks of the BARRICAID\* surgery combined with the conventional treatment are: a) infection of wound/drainage; 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 or out the lumbar disc; f) death as complication of the surgery or anesthesia

## Contacts

### Public

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### Scientific

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## 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 and S1 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 physical therapy, use of anti-inflammatory medications at maximum specified dosage and/or administration 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 willing to adhere to follow-up schedule and requirements.

## Exclusion criteria

3.1.2 EXCLUSION CRITERIA Any subject meeting any one of the following criteria will be excluded from enrollment into the trial:

1. Spondylolisthesis Grade II or higher
2. Subject requires uni or bilateral facetectomy to treat leg/back pain
3. Subject has back or non-radicular leg pain of unknown etiology.
4. Prior fusion (with or without instrumentation), motion preservation, facetectomy or IDET surgery at the index lumbar vertebral level
5. Subject\*s requiring a spine DEXA (i.e., patients with SCORE of = 6) with a T Score less than -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 vertebra or 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