A prospective randomized multicenter study to demonstrate the superiority of the Barricaid® to discectomy for primary lumbar disc herniation: Extended Follow-Up of the Barricaid® Annular Closure Device (ACD) Randomized Control Trial (RCT) Postmarket Cohort for Lumbar Disc Herniation and Interaction with Other Risk Factors

Published: 14-03-2011
Last updated: 19-07-2024

The purpose of this post-approval protocol amendment is to extend the follow-up of subjects who were originally enrolled in theRCT, EUBARD-CP_001 protocol. This study extension will examine the long-term survivorship of the Barricaid® ACD when...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational invasive

Summary

ID

NL-OMON55882

Source
ToetsingOnline

Brief title
EUBARD*CP*011

Condition

- Tendon, ligament and cartilage disorders
- Spinal cord and nerve root disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
lumbar disc herniation, sciatica

Research involving
Human

Sponsors and support

Primary sponsor: Intrinsic Therapeutics, GmbH
Source(s) of monetary or material Support: Intrinsic Therapeutics;GmbH (bedrijf)

Intervention

Keyword: annular closure, long-term follow-up, lumbar disc herniation, reherniation

Outcome measures

Primary outcome

The primary hypotheses of this extended follow-up post approval study extension

are:

• The Barricaid® ACD remains safe and effective at 10 years.

• The Barricaid® ACD subjects do not have late or continued slow growth of

lesions that lead to new or unexpected AEs or

adverse clinical outcomes.

• Development of osteoporosis does not negatively impact the progression of

lesions observed and does not lead to new or

unexpected AEs or adverse clinical outcomes.

Sample size: This study extension is not powered to demonstrate statistical

conclusions, but rather the sample size is based on

the subjects from the original 2-year study who agree to participate in longer-term follow-up.

Secondary outcome

Long term survivorship will be determined through the evaluation of

1. Device- or procedure-related Serious Adverse Event (SAE)

2. Secondary surgical interventions at the index level

Clinical and radiographic endpoints including both symptomatic and asymptomatic reherniations, specified in the data collection sections below may be used in post-hoc analyses between treatment arms. Specifically, growth and size measurements will be used to monitor development and progression of new and existing lesions.

The safety will be supported if the incidence of secondary surgical interventions (SSIs) and the incidence SAEs related to either the device or procedure is not greater in the Barricaid® ACD cohort than in the Control cohort.

Adverse events will be evaluated by an independent DSMB. Adverse events will be categorized as device-related and/or procedure-related and will be assigned severity or seriousness. Safety will be determined by evaluating the type, frequency, severity, and relationship to device and/or procedure of adverse events through the 10 and 13 year time point. Stability in this study extension is defined as less than 35mm2 change in any individual endplate lesion size between follow-up timepoints. Adverse event type will include events specific to the observation

and/or consequence of endplate lesions.

Study description

Background summary

Low back pain and sciatica is often associated with herniation of a lumbar disc. In the Western society, up to 25 percent of the population may experience a combination of low back pain or sciatica at some point in life. If conservative treatment is not successful, surgery may be indicated. Lumbar discectomy for the treatment of radicular pain from a herniated lumbar disc is one of the most frequently performed surgical procedures (12,000 operations annually in the Netherlands). Despite the efficacy of this operation for leg pain, many patients (7-36%) suffer from persistent low back pain, and 5-18% will have a recurrent disc herniation requiring surgery. This subgroup of patients has a high risk of ending up with chronic low back pain, and place a high financial burden on society because of costs for medical care and economic loss.
The Barricaid® ARD was developed in an effort to minimize the risk of recurrence of sciatica, back pain and disc herniation following a lumbar discectomy. The Barricaid® ARD is a CE-marked permanent implant aimed at reconstruction of the posterior wall of a bulging disc annulus that has been treated by limited discectomy. The device acts as an internal mesh closing the interior surface of the defect in the disc annulus, thus preventing reherniation of the disc nucleus. By restoring the integrity of the posterior annulus, the Barricaid® should help to prevent recurrent disc herniation, loss of disc height with ensuing back pain and sciatica.
A Prospective, Randomized, Multicenter Study to Demonstrate the Superiority of the Barricaid® to Discectomy for Primary Lumbar
Disc Herniation: Extended Follow-Up of the Barricaid® Annular Closure Device (ACD) Randomized Control Trial (RCT) Postmarket
Cohort for Lumbar Disc Herniation and Interaction with Other Risk Factors
The Barricaid® Anular Closure Device was approved for marketing in the United States by the FDA on February 8, 2019
(P160050). As a condition of approval, the manufacturer agreed to conduct a long-term follow-up on all patients enrolled in the
randomized controlled trial (RCT) titled: A Prospective, Randomized, Multicenter Study to Demonstrate the Superiority of the
Barricaid® to Discectomy for Primary Lumbar Disc Herniation (EUBARD-CP-001).
The original protocol was approved and instituted at 21 sites and enrolled 554 study subjects. Enrollment of subjects lasted from
December 2010 to October 2014. Subjects were originally scheduled to be followed until the last patient enrolled in the trial
reached their 24 month follow-up. Subsequently, all ECs approved a protocol

addendum that allowed all patients to be followed for
a total of 60 months (5 years).
Study endpoints of the original protocol included radiographic and clinical outcomes including reherniation, reoperation, pain, and
disability. Components of the radiographic evaluations included Modic changes, device integrity, disc height, and endplate changes
(EPCs). EPC frequency, size, change in growth, and correlation to clinical outcomes were evaluated. To date, there have been no
serious adverse events associated with EPCs in the Barricaid patient cohort.

Study objective

The purpose of this post-approval protocol amendment is to extend the follow-up of subjects who were originally enrolled in the
RCT, EUBARD-CP_001 protocol. This study extension will examine the long-term survivorship of the Barricaid® ACD when used
in conjunction with limited discectomy. This study extension is also intended to monitor the natural history of endplate lesions due
to interactions with the device, potential interactions with the development of osteoporosis, lesion growth and lesion stability. The
study is also intended to investigate potential underlying mechanisms that may contribute to any additional growth through retrieval
analysis and histological analysis of peri-prosthetic tissue.

Study design

Postmarket Cohort documenting the Extended Follow-Up of the Barricaid® Annular Closure Device (ACD) Randomized Control
Trial (RCT) in patients undergoing a limited discectomy for Lumbar Disc Herniation
This is a prospective, controlled, continued long-term follow-up evaluation of patients originally randomized into the RCT,
EUBARD-CP-001.

Intervention

Barricaid® group:
primary lumbar microdiscectomy followed by implantation of the Barricaid device in the posterior annulus defect.

Control group:
primary lumbar microdiscectomy alone (Spengler, 1982), without placement of Barricaid.

Study burden and risks

This post-approval protocol would follow all subjects through 10 years (10 and 13 year timepoints) with follow-up estimated to be completed in December, 2025.
• 10/13 year follow-up contact:
o Patient questionnaires (VAS, ODI)
o Adverse event evaluation
o Symptomatic reherniation
o AP/lateral, Flex/Ex, lumbar MRI, low dose CT at index level
* Device Subsidence
* Endplate Lesions - size and growth measurements
* Device Condition/Migration
* Reherniation at index level

o 10 year only: SCORE questionnaire. Femoral neck DEXA scan if required per SCORE osteoporosis screening questionnaire (subjects with SCORE of >= 6)

This study includes the use of MRI, X-Ray, CT, and DEXA scans which are not part of the standard treatment in these subjects.
In the informed consent, the discomfort and risk of the MRI, X-rays, CT and Dexa is explained. MRI may cause discomfort, claustrofobia, ear protection should be worn and there might be unknown negative effects of the electromagnetic fields. For the Xray investigations, including the low dose CT, the amount of radiation involved is explained and put into perspective: it is equal to an amount every person is subjected over the course of 2-3 months: 0,54mSv. For the CT investigation, there may also be discomfort and claustrofobia. Finally, a Dexa scan only causes a small amount of radiation, less than the ampount received in one day.
This long-term follow-up of subjects who were originally enrolled in the RCT, EUBARD-CP_001 protocol will examine the long-term survivorship of the Barricaid® ACD when used in conjunction with limited discectomy. This study extension is also intended to monitor the natural history of endplate lesions due to interactions with the device, potential interactions with the development of osteoporosis, lesion growth and lesion stability. The study is also intended to investigate potential underlying mechanisms that may contribute to any additional growth through retrieval analysis and histological analysis of peri-prosthetic tissue. This research is justified to investigate whether the benefits of the Barricaid annular closure device used in conjunction with a limited discectomy, as compared to limited discectomy only, as demonstrated at the 2 and 5-year follow-up intervals, can indeed be confirmed over a longer period of time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Only subjects enrolled in the original RCT protocol EUBARD-CP-001 will be eligible for long-term follow-up.
Original inclusion criteria included: subjects with radiculopathy (with or without back pain), a positive straight leg raise (L4-5, L5-S1) or femoral stretch test (L1-2, L2-3, L3-4), and a posterior or posterolateral herniation at one level between L1 and S1 with radiographic confirmation of neural compression using MRI who are found to have an anular defect (post discectomy) which measures between 4mm and 6mm tall and between 6mm and 10mm wide, with a minimum posterior disc height of 5mm, and failed at least 6 weeks of conservative treatment.

Exclusion criteria

Only subjects enrolled in the original RCT protocol EUBARD-CP-001 will be eligible for long-term follow-up.
Subjects who have died or withdrawn consent during follow-up of RCT EUBARD-CP-001 will not be included in the patient population eligible for this long-term evaluation.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2011
Enrollment:	66
Type:	Actual

Ethics review

Approved WMO Date:	14-03-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-11-2011

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-02-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-02-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NCT01283438
CCMO	NL32866.029.10

Study results

Results posted: 01-06-2016

First publication
26-05-2015