Post-Market Data Collection for Treatment of Avascular Necrosis (AVN) of the Femoral Head With Core Decompression Using the PerFuse Instrument and BioCUE

Published: 09-06-2016
Last updated: 16-04-2024

The objective of the study is to characterize the performance of biologically assisted core decompression performed with the PerFuse instrument and BioCUE for the treatment AVN of the femoral head. The study will explore the potential impact of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON47602

Source
ToetsingOnline

Brief title
AVN Perfuse BioCUE Study

Condition

- Joint disorders

Synonym
Avascular Necrose; Death of bone tissue

Research involving
Human

Sponsors and support

Primary sponsor: Biomet Biologics (Zimmer Biomet)
Source(s) of monetary or material Support: Biomet Biologics

Intervention

Keyword: ARCO 1-2, Avascular Necrosis, Core Decompression

Outcome measures

Primary outcome

Percentage of patients achieving clinical success at 12 months after initial study procedure. For the purpose of the study, clinical success is defined as an increase of HHS of more than 20 points from baseline.

Secondary outcome

- Number of patients with no change or decrease in lesion size measured via MRI at 12 months after the index procedure compared to baseline

- Number of hip collapses requiring an invasive procedure other than study treatment

- Measure the number of adverse events of interest at 3, 6, 12, 24, 36, 48 and 60 months after the index procedure

- Change in HHS, pain measured with the NRS and quality of life scores measured with EQ-5D-3L 3, 6, 12, 24, 36, 48, and 60 months after the index procedure

- Number of patients with *good* or *excellent* HHS at all post-operative time points

- Cost of healthcare associated with AVN treatment

- Number of study procedures per patient

Study description

Background summary

Avascular necrosis (AVN) is a disease that affects weight bearing joints, most commonly, the hip (Gangji & Hauzeur, 2010). AVN of the femoral head is associated with chronic or high dose corticosteroid use, alcohol abuse, trauma, sickle-cell disease, organ transplant, smoking and chronic diseases such as renal disease, hematologic disease, inflammatory bowel disease, systemic lupus erythematosus and HIV. AVN of the femoral head typically presents between the ages of 20 and 40 (Gangji et al., 2010). Left unchecked, AVN of the femoral head can lead to collapse and the need for total hip arthroplasty (THA). Due to the young to middle-aged patient population, a joint saving procedure that prevents or postpones THA is needed. This is especially true for patients with sickle cell disease as 90% of those with AVN experience femoral head collapse within 2 years of diagnosis and also tend to have higher failure rates and complications with THA (Neumayr et al., 2006). Current options to halt the progression of AVN include core decompression, osteotomy and medications however up to 40% of patients continue to progress to THA.

Core decompression (CD) has been used for several decades as a joint-preserving method to decrease pressure and pain in the necrotic lesion (Koo et al., 1995) and is the most common treatment for pre-collapse AVN (McGrory et al., 2007). In patients with AVN, it is thought that there is a lack of progenitor cells in the location of the femoral head and proximal femur making the body unable to heal the lesion. In order to improve the outcomes, CD has been combined with the injection of stem cells obtained from bone marrow aspirate to re-populate the lesion with host progenitor cells. (Houdek, Wyles, Martin, & Sierra, 2014)

Several studies have been completed in cohorts of varying size showing promising results with biologically assisted CD (Tabatabaee, Saberi, Parvizi, Mortazavi, & Farzan, 2015). This study will evaluate the performance of biologically assisted CD performed with the PerFuse instrument and output from the BioCUE Concentration System. PerFuse features a small (6 mm) cannula advanced with a mallet for decompression of the lesion which allows for post-operative weight bearing. There is no need to decompress with a reamer which can heat the tissues potentially causing damage.

Study objective

The objective of the study is to characterize the performance of biologically assisted core decompression performed with the PerFuse instrument and BioCUE for the treatment AVN of the femoral head. The study will explore the potential impact of patient demographics and baseline characteristics on treatment outcome. In addition, the utilization of healthcare resources and associated

costs will be investigated in treated patients.

Study design

This multicenter, observational study will be executed in up to 10 centers in the United States and Europe. A maximum of 100 patients will be included. Patients with avascular necrosis (AVN) in the femoral head meeting the eligibility criteria will be invited to participate in the study.
Participating patients will undergo the procedure as per Instructions for Use of the PerFuse instrument and the BioCUE Concentration System (CE marked, within label). Patients may undergo up to two procedures per hip, but the initial procedure will remain the index for the follow-up scheme. Patients will be followed-up for 60 months, and questionnaires will be completed at 3, 6, 12, 24, 36, 48 en 60 months after the initial procedure.
The patients will be followed in the study until one of the following study completion criteria occur:
- Invasive procedure other than study procedure required
- Completion of 60 months of follow-up after the initial procedure
- Death, Withdrawal or Lost to follow-up

Intervention

The study procedure will be performed in accordance with the geographical location
specific surgical technique described in Appendix 2 and in accordance with the geographical location specific Manufacturer*s Instructions For Use (IFU) (Appendix 1) with one exception for European sites. European sites will use three
standard BioCUE tubes instead of two standard BioCUE tubes plus one standard GPS III tube.

A rehabilitation protocol will occur per standard of care protocol at the participating
center and details of this protocol will be documented in order to evaluate the effect
of the post-procedure care and rehabilitation protocol on the outcome of the treatment.

Study burden and risks

According to the standard of care in this center patients can choose to be treated with the PerFuse-system and BioCUE even without participation in this study. Risks associated with these commercially available devices are described in the Instructions for Use. Since the PerFuse and BioCUE are used as standard of care in this center, these risks are not additional risks as a result of study participation.

If a patient participates in the study, besides the study treatment and the standard MRI, the patient will be asked to complete some questionnaires at predefined time points over a period of 60 months. Additionally, at 12 months after the procedure an extra MRI will be taken for the study. The questionnaires can be completed by phone or online or in the hospital. The patient will be asked to visit the hospital one additional time compared to the standard procedure for the extra MRI.

The additional risks and burden due to participation in the study consist of discomfort when answering some of the questions on the surveys, and risks associated with MRI.

Risks associated with MRI imaging are the following:
- The magnetic field used by MRI scanners may cause malfunction or heat up of implanted
- medical devices that contain metal during the exam.
- Any loose metal object may cause damage or injury if it gets pulled toward the magnet.
- Dyes from tattoos can cause skin irritation after an MRI exam.
- Medication patches can cause skin burns.
- Prolonged exposure to radio waves during the scan could lead to slight warming of the body
- but this is rare.
- Patients may have some anxiety due to being in a confined space.

The MRI technician will help the patient to minimize the risks as much as possible. Taking MRIs is a standard procedure at the center.

Therefore, the opinion of the sponsor is that the risk due to study participation are negligible.

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

- Physician agrees that patient is good candidate for procedure
- At least 18 years of age
- Willing and able to comply with the study procedures
- Signed informed consent form
- If bilateral untreated AVN, eligible and willing to undergo study treatment and follow-up for both hips
- If contralateral hip has undergone a THA surgery, 3 months of time must have passed since THA before performing the study procedure

Exclusion criteria

- Pregnant or lactating
- Participating in another device or drug study
- AVN stage (ARCO) * 3
- Unable to undergo MRI of the study hip(s)
- Active or chronic infection

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-10-2016
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	PerFuse and BioCue
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	09-06-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	04-08-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	06-12-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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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	NL57440.098.16

Study results

Date completed: 31-01-2020

Actual enrolment: 5

Summary results
Trial ended prematurely