Study in knee osteoarthritis treated by embolization using NBGM200

Published: 07-05-2024
Last updated: 07-06-2025

The objective of this study is to accumulate clinical data on the safety and performance of NBGM200 embolization in patients with degenerative OA of the knee refractory to conservative treatment so as to provide evidence of conformity with…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON57239

Source
ToetsingOnline

Brief title
Study in knee osteoarthritis treated by embolization using NBGM200

Condition

- Joint disorders

Synonym
Lay term: Knee pain / Medical term: Knee degenerative osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: NEXTBIOMEDICAL CO., LTD.
Source(s) of monetary or material Support: NEXTBIOMEDICAL CO., LTD.

Intervention

- Medical device

Keyword: 1) Osteoarthritis, 2) Embolization, 3) Musculoskeletal, Knee, Therapeutic

Explanation

N.a.

Outcome measures

Primary outcome

Percentage of patients achieving clinical success, defined as a 30% or greater reduction from baseline in KOOS-12 at 6 months.

Secondary outcome

• Change from baseline in pain relief (VAS) at 6 months post-procedure.
• Percentage of patients achieving clinical success, defined as a 30% or greater reduction from baseline in WORMS at 6 months.

Study description

Background summary

Osteoarthritis(OA) is one of the major causes of pain and disability, where sensitive nerves and sensory nerve hypersensitivity in the inflamed areas due to cartilage destruction promote the formation of new blood vessels, and these new blood vessels stimulate surrounding nerve cells, causing and worsening pain. In the United States, 26.9 million adults suffer from OA, and it is estimated that 50% of adults will develop severe knee osteoarthritis by the age
of 85.

Treatment for knee OA includes exercise, education, and pharmacological therapies, including oral, topical, and intra-articular medications. Mild symptoms can be managed with nonsteroidal anti-inflammatory drugs (NSAIDs), but severe or end-stage osteoarthritis is treated with total joint arthroplasty. However, NSAIDs can cause renal failure and, notably, gastrointestinal bleeding, highlighting the need for new, effective, minimally invasive, and safe treatments for knee osteoarthritis.

Among these, particulate embolization has been reported as a safe method for treating bleeding after total knee arthroplasty. Particulate embolization has been effective in reducing

pain in seven patients with refractory tendinopathy and enthesopathy, with no major complications. Additionally, synovial embolization in a study of 14 osteoarthritis patients showed pain reduction and decreased difficulty in movement, with no complications. Recent studies have shown that in 72 osteoarthritis patients, successful procedures were performed, with clinical success rates of 86.3% at 6 months and 79.8% at 3 years, and MRI follow-up showed no signs of osteonecrosis or degenerative changes.

NBGM200 is Class III embolic material that is resorbable within 2-8 hours, or/and the rate of resorption can be tuned depending on the type of intervention, and is intended for use in embolization arteries. In addition, If microcatheter embolization(TAME) to OA knee patients is performed using NBGM200, it is possible to treat the patient's pain by blocking hypervascularization (angiogenesis) and inducing the death of nerve cells that cause pain.

Consequently, it is the only product that can control resorption time and is a high-elasticity, high-density, and high-cohesive embolic agent product optimized for microvascular embolism. NBGM200 is an embolic material composed of gelatin and has a spherical shape and is harmless to the human body because no chemical crosslinking agent is used during manufacturing.

The reason for setting a 6-month follow-up period in this study is that several studies have demonstrated that data collected over 6 months is suitable for evaluating pain improvement. For example, YS Bagla et al. (2019) and B Wang et al. (2023) evaluated the effects of pain improvement over a 6-month period, and Y Okuno et al. (2013) evaluated it over 4 months. In particular, a 6-month follow-up period is widely used in arthritis research to effectively assess the degree of pain relief.

This study has set a 6-month follow-up period to evaluate the pain relief effect and safety of the biodegradable product NBGM200. The data collected during this period is sufficient to evaluate the initial effects of the treatment, considering the feasibility of the study and resource constraints.

Given the study's resources and costs, a 6-month follow-up period is a realistic choice that minimizes the burden on the study while allowing for effective evaluation. The results of this initial study will serve as baseline data for evaluating long-term effects in future research. Future studies will aim to more clearly assess long-term effects based on this data.

Therefore, the 6-month follow-up period is considered appropriate for the study's objectives and sufficient for evaluating the pain improvement effect. The overall study design is structured to reduce the burden on patients and proceed as efficiently as possible.

The proposed 6-month follow-up period in this study may pose a significant burden on participants. However, considering the objectives of the study and the potential benefits, participants can expect pain relief during the study period. Participants may also anticipate long-term improvements in their quality of life by participating in this study, in addition to short-term pain relief. The expectation that the effects may last for about a year is important information.

Moreover, the research procedures will be designed in such a way that the burden associated with the benefits is not excessive. Participants will receive adequate information and support throughout the study period. Given the positive outcomes that may result from participation, the benefits and procedures of the study can be balanced against the potential burden.

Study objective

The objective of this study is to accumulate clinical data on the safety and performance of NBGM200 embolization in patients with degenerative OA of the knee refractory to conservative treatment so as to provide evidence of conformity with Regulation (EU) 2017/745 to obtain a CE certification.

Study design

Prospective, Single-arm, Multinational, Multi-center clinical study

Intervention

NBGM200, developed by NEXTBIOMEDICAL CO., LTD., is Class III embolic material that is resorbable within 2-8 hours, or/and the rate of resorption can be tuned depending on the type of intervention, and is intended for use in embolization of arteries. In addition, it is the only product in the world that can control resorption time and is a high-elasticity, high-density, and high-cohesive embolic agent product optimized for microvascular embolism. It is an embolic material composed of gelatin and has a spherical shape and is harmless to the human body because no chemical crosslinking agent is used during manufacturing. Musculoskeletal Embolization (MSKE) can cause various side effects (skin discoloration, necrosis) because the blood vessels in the treated area are thin and close to the skin. However, since NBGM200 temporarily occludes blood vessels, it is very unlikely to cause tissue necrosis or skin discoloration. In the case of non-degradable embolic agents, tissue necrosis and skin discoloration have been reported as side effects of embolization, whereas in the case of NBGM200, side effects such as skin discoloration or skin ulceration have not occurred in patients who have undergone embolization so far. This clinical investigation is designed to accumulate clinical data on the performance and safety of NBGM200 in patients with knee degenerative osteoarthritis.

Study burden and risks

During the six-month clinical trial, participants will undergo various examinations and examinations such as follows:
- one blood analysis and pregnancy test (using minimal amount of blood and urine),
- two physical examinations,
- three vital signs measurements,
- one medical/surgical history survey,
- one demographic survey,
- one X-ray scan (radiation dose 0.005 mSv),
- two MRI scans,

- eight surveys for concomitant drugs and treatments,
- eight surveys for VAS, KOOS-12,
- and adverse reactions.
These may cause temporary physical/physiological discomfort or unexpected adverse events. However, embolization has the advantage of reducing knee pain that does not respond to conservative treatment, and this improvement in knee pain can last for more than a year on average.

Contacts

Scientific
NEXTBIOMEDICAL CO., LTD.
Subin Yu
Venture-ro 100beon-gil 6
Incheon 22013
South Korea
82324544822
Public
NEXTBIOMEDICAL CO., LTD.
Subin Yu
Venture-ro 100beon-gil 6
Incheon 22013
South Korea
82324544822

Trial sites

Trial sites in the Netherlands

Elisabeth-Tweesteden ziekenhuis
Target size: 42

Listed location countries

Belgium, Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients must satisfy all of the following inclusion criteria.
1) Adult men and women aged 50 years and over.
2) Osteoarthritis proven by MR-imaging.
3) Kellgren-Lawrence (KL) grade 1-3.
4) Visual Analogue Scale (VAS) pain score of >=5 (on a scale of 0 to 10).
5) Patients who do not respond to conservative therapies (including exercise, weight loss, pharmacological agents, transcutaneous electrical nerve stimulation, knee bracing, foot orthoses, thermotherapy, oral supplements, or dry needling) for at least 24 weeks prior to receiving Musculoskeletal Embolization (MSKE).

Exclusion criteria

Patients with one or more of the following criteria should not be included in this trial.
1) Significant intra-articular lesions that could be the cause of complaints or KL grade 4 OA.
2) Current local infection.
3) Life expectancy less than 6 months.
4) Known advanced atherosclerosis, with known lower extremity vascular or lower extremity symptoms thought to be secondary to arterial vascular disease (e.g., claudication or ischemic rest pain).
5) Rheumatoid or infectious arthritis.
6) Prior knee replacement surgery on the target knee at any time.
7) Knee surgery on the target knee within the past 10 years (procedures such as micro-perforation or cartilage repair).
8) Uncorrectable coagulopathy including INR > 2.5 or platelets < 30,000/µL.
9) Iodine allergy resulting in anaphylaxis.
10) Renal dysfunction as defined by GFR (eGFR) of <45 mL/min/1.73m2 obtained within the past 60 days.
11) Ligament ruptures.
12) Contraindications for MR Imaging (such as claustrophobia, metallic fragment or foreign bodies implants, or prosthesis).
13) Dementia.
14) Pregnancy or breastfeeding.
15) Gelatin allery resulting immun reaction.
16) Other cases where participation in this clinical trial is judged inappropriate according to the judgment of the investigator.
17) No “Blush” is seen on the angiography and who do not experience “Pain” in the area concerned.

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-04-2025
Enrollment:	42
Duration:	7 months (per patient)
Type:	Actual

WORLD

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2025
Enrollment:	72
Type:	Actual

Medical products/devices used

Product type:	Medical device
Generic name:	NBGM200
Registration:	No

IPD sharing statement

Plan to share IPD: Yes

Plan description
To protect the patient's privacy, we always use only code for data management. Even in reports and publications about the study, nobody will be able to see the information related

to privacy.

Ethics review

Approved WMO Date:	23-01-2025
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-04-2025
Application type:	Amendment
Review commission:	MEC-U

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	NL 85909.000.24
CCMO	NL85909.000.24
Research portal	NL-005100