Prospective, Post-market Evaluation of Safety and Efficacy of a Local Osteo-Enhancement Procedure (LOEP) in the Proximal Femur of Women in Europe With Osteoporosis

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51693

Source
ToetsingOnline

Brief title
RECONFIRM

Condition

- Other condition

Synonym
osteoporosis, proximal femur bone mineral density

Health condition

proximal femur with high risk for fragility fracture

Research involving
Human

Sponsors and support

Primary sponsor: AgNovos Healthcare
Source(s) of monetary or material Support: industry

Intervention

Keyword: Bone mineral density, LOEP, osteoporosis, proximal femur

Outcome measures

Primary outcome

The primary performance endpoint is 6% increase in mean femoral neck BMD from pre-procedure baseline to 12 months post-procedure of treated hips.

The primary safety evaluation is the incidence of all adverse events and serious adverse events occurring post-AGN1 LOEP through the 12 months follow-up period determined to be at least possibly related to the procedure and/or device.

Secondary outcome

The secondary performance endpoints are:

• 6% increase in mean total hip BMD from pre-procedure baseline to 12 months post-procedure of treated hips.

• 6% increase in mean femoral neck BMD from pre-procedure baseline to 24 months post-procedure of treated hips.

• 6% increase in mean total hip BMD from pre-procedure baseline to 24 months post-procedure of treated hips.

Additional outcomes are:

• Radiologic appearance of bone formation as assessed by X-ray at 12 and 24 months post-procedure of treated hips.

• Patient satisfaction with outcome of surgery in the treated hip(s) and overall at 42 days and 12 months

• VAS (left hip, right hip, body overall) at baseline, 42 days, 12 months, and 24 months

• FES-I at baseline, 42 days, 12 months, and 24 months

• EQ5D-5L at baseline, 10 days, 42 days, 12 months, and 24 months

• Parker Mobility Score at baseline, 10 days, 42 days, 12 months, and 24 months

• The ability to access the enhancement site and to determine the boundaries of the enhancement site.

• The ability to deliver the necessary amount of AGN1 material to adequately fill the osseous defect as assessed by the treating surgeon.

• Incidence of all serious adverse events post-AGN1 LOEP through the 24 months follow-up period.

• Incidence of new hip fractures on the treated side.

• Timed up and go test at baseline, 10 days, 42 days and 12 months

Study description

Background summary

Fragility fractures of the hip (i.e. a fracture resulting from a low-energy trauma such as a fall from standing height) are associated with significant morbidity and mortality, and represent a significant burden on affected individuals, families, and healthcare systems. Multiple experts and groups have called the current situation a *crisis* and have called for urgent action and development of alternative strategies to reduce the risk of hip fractures due

to osteoporosis. Although multiple factors contribute to hip fracture risk, a key factor is osteoporosis, a disease characterized by reduced bone mass. The loss of trabecular bone caused by osteoporosis is particularly problematic in the hip where a fracture results in the highest morbidity of all fragility fracture locations. By restoring lost trabecular bone, the weakened area is strengthened, resulting in increased force required to produce a fracture, thereby reducing the risk of fracture. Other factors (e.g., age, malnutrition, visual acuity, falls and dementia) also play a role in determining fracture risk. Due to these risks, fragility fractures of the hip predominantly affect the elderly, particularly postmenopausal women who experience more dramatic declines in bone mass than men due to hormonal differences.

Study objective

The primary objective of the study is to evaluate the post-market safety and BMD improvement of AGN1 LOEP in patients with osteoporosis in at least one hip. The secondary objective is to evaluate the post-market functional measures of clinical performance and patient satisfaction of the AGN1 LOEP.

Study design

Prospective, post-market, multi-center study. The study will collect procedural, short- and long-term data on the safety and clinical performance of AGN1 LOEP in the post-market setting.

Intervention

Local osteo-enhancement procedure (LOEP)

Study burden and risks

AGN1 LOEP treatment is expected to have a significant benefit for patients with osteoporosis due to the critical unmet need and large gap in treatment options. Once the AGN1 LOEP treatment is completed, the AGN1 implant material immediately increases strength of the treated proximal femur. The implant material is resorbed by the body and replaced with bone to provide long-term improved strength. By forming new bone in the proximal femur, there is an expected increased resistance to a hip fracture during a patient fall. This increased resistance to fracture should reduce the risk and incidence of hip fractures.

Risks associated with AGN1 LOEP can be anticipated by examining the risks that apply to surgeries with similar technical complexity and clinical experience with the AGN1 LOEP treatment itself. In addition, use of the AGN1 implant material may be associated with risks. Specific risks may include:
• Wound complications including infection, hematoma, site drainage, tissue

irritation, and other complications that are possible with any surgery
• Venous thrombosis and sequelae
• Fat emboli and sequelae
• Material extravasation into vessels/emboli and sequelae
• Fracture or extrusion of the AGN1 implant material, with or without particulate debris generation
• Deformity of the bone at the site
• Incomplete, or lack of, osseous ingrowth into the implantation site
• Transient hypercalcemia
• Proximal femoral fracture
• Pain at the treatment site
• Death
AGN1 LOEP will be performed under anesthetic, the type of which will be at the discretion of the treating physician depending on the patient profile. The use of anesthesia brings risks that vary depending on type, route and dose of administration. The risks of undergoing anesthesia and/or sedation have been well established in the medical community. No additional risks to anesthesia complications have been noted for undergoing AGN1 LOEP; however, the established risks of anesthesia and/or sedation are still possible and should be discussed with the study subjects prior to the procedure.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

1. Subject is a postmenopausal female (at least 1-year post menses).
2. Subject has bone loss in the hip attributable to osteoporosis as defined by a femoral neck DXA T-score of -2.5 or less.
3. Subject has at least one hip without previous surgery or fracture.
4. Subject is medically stable from any previous treatment or medical procedure in the opinion of the investigator and with an ASA score of I or II.
5. Subject has willingness, ability, and commitment to participate in baseline and follow-up evaluations for the full length of the study.
6. Subject is capable of giving written informed consent to participate in the study.

Exclusion criteria

1. Subject is less than 3 months removed from having a hip fracture repair or prosthesis or elective Total Hip Arthroplasty (THA).
2. Subject has progressive increase in hip pain over the previous six (6) months that in the opinion of the Investigator suggests moderate to severe intra-articular arthritis, labral tear, extra-articular soft tissue pathology, referred pain, tumor, stress fracture or infection.
3. Subject is dependent on the use of a wheelchair or is bedridden.
4. Subject has albumin corrected serum calcium levels outside the normal lab range or has a pre-existing calcium metabolism disorder (e.g., hypercalcemia)
5. Subject has severe renal insufficiency defined as an estimated glomerular filtration rate (eGFR) < 30 mL/min or is being treated with dialysis
6. Subject has hemoglobin A1c level >= 7.5%.
7. Subject has Body Mass Index (BMI) > 35.
8. Subject exhibits excessive smokeless tobacco use or excessive smoking as determined by the principal investigator*.
9. Subject is at ASA Class III, IV, V or VI.
10. Subject exhibits excessive alcohol consumption as determined by the principal investigator*.
11. Subject has radiological evidence of gross bony or joint pathology of the hip, including signs predictive of atypical femoral fractures (e.g., Cortical beaking) or has been diagnosed and/or treated for atypical femoral fractures.
12. Subject treated with corticosteroids or systemic glucocorticoids for ten (10) days in the previous six (6) months.

13. Subject has history of oral or parenteral use of immune-suppressive drugs in the previous twelve months.
14. Subject has history of metabolic bone disease other than osteoporosis (ex. Paget*s disease).
15. Subject has a history of auto-immune hip arthritic diseases including rheumatoid, psoriatic, or those associated with systemic lupus erythematosus, spondyloarthropathy, Reiter*s Syndrome or Crohn*s Disease.
16. Subject has a history of radiation therapy to the hip or pelvic region.
17. Subject has a history of any invasive malignancy (except basal cell carcinoma), unless treated and with no clinical signs or symptoms of the malignancy for five (5) years.
18. Subject has known allergies to implanted device.
19. In the judgement of the Investigator, the subject is not a good study candidate (e.g., inability to maintain follow-up schedule, comorbidity or poor general physical/mental health, or drug or alcohol abuse issues).
20. Subject is currently enrolled in another clinical study.

*AgNovos*s recommendation is >1 pack per day smoking and >3 alcoholic drinks per day

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-02-2023
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	AGN1 Local Osteo-Enhancement Procedure Kit
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-11-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-06-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-12-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NCT05202678
CCMO	NL80812.075.22