Clinical Evaluation of the Safety of a Local Osteo-Enhancement Procedure (LOEP) Intended to Increase Bone Strength in the Proximal Femur of Women in Europe with Osteoporosis.

Published: 23-08-2017
Last updated: 13-04-2024

To conform the procedural safety of the OSSURE LOEP Kit in the specific clinical setting of use in the femoral neck in patients with osteoporosis. Secondary objective: To evaluate the post-market clinical performance of the OSSURE LOEP Kit.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON49592

Source
ToetsingOnline

Brief title
CONFIRM Europe

Condition

- Bone disorders (excl congenital and fractures)

Synonym
bone weakening, osteoporosis

Research involving
Human

Sponsors and support

Primary sponsor: AgNovos Healthcare USA, LLC
Source(s) of monetary or material Support: Industry: sponsor: AgNovos Healthcare USA;LLC

Intervention

Keyword: Hip, LOEP, Osteoporosis

Outcome measures

Primary outcome

The incidence of all adverse events occurring during the first forty-two (42)

day follow-up period determined to be at least possibly related to the

procedure and/or device for the local treatment of osteoporosis.

Secondary outcome

• The ability to deliver the necessary amount of OSSURE material to fill the

osseous defect as assessed by the treating doctor.

• The ability to access the intended treatment site and successfully inject the

material.

Study description

Background summary

Osteoporosis is the most common bone disease worldwide and is the main underlying cause of fractures in postmenopausal women and the elderly (prevalence increased due to aging). Bone fractures occur mainly because the bone strength is no longer sufficient, the most foremost locations are: the vertebral column, the wrist and the hip. Current treatment for osteoporosis is to inform patients in combination with nutrition, movement and medication. Despite current therapy, there is still an increase in hip fractures due to osteoporosis. The LOEP increases bone growth, enhancing the hip. Because this occurs only in part of the hip, it is not a substitute for current therapy but

rather a supplement.

Study objective

To conform the procedural safety of the OSSURE LOEP Kit in the specific clinical setting of use in the femoral neck in patients with osteoporosis.

Secondary objective: To evaluate the post-market clinical performance of the OSSURE LOEP Kit.

Study design

The CONFIRM study is a prospective, Multi-centre, non-randomised and non-blinded study with a medical device (OSSURE LOEP kit) for the treatment of osteoporosis, In total a maximum of 60 patients will participate in the study in different sites within Europe.

Intervention

The medical device is the OSSURE LOEP Kit (i.e., kit for local strengthening of the proximal (upper) femur, which means hip). Part of this product is a synthetic (i.e., man-made), calcium-based implant. The components of the implant are similar to components of normal bone.

The intervention is performed under sedation or local anesthesia (dependin ont eh patient) and will take about 60 minutes.The physician will make an incision on the outer side of the tight and will drill until they reach the space in the femoral neck. The femoral neck of osteoporotic patients
contains poorly-connected and non-load bearing trabecular bone, fluid, fat, and marrow elements. This non-structural tissue is then removed using a probe debrider, irrigation and suction. The AGN1 implant device is placed inside a delivery syringe and manually injected under low pressure delivered into the injection site.

Study burden and risks

There are several risks and inconveniences associated with participation in the procedures and tests required in this clinical trial, like blood sampling, DXAscan, CT scan (optional) and X-Ray. There are also risks similar to those associated with other hip procedures, like pain, irritation, infection, blood vessel injury, implant leakage, blood clots, wound problems, hip fracture, break down of bone.
However it is believed that patients that are not participating in the study also underdo most of these assessments and procedures and are therefore exposed to similar risks.

Patiënts can continue their standard of care treatment, the study procedure is additional to the standard of care. The investigational medical device may increase the strength of the hip bone and potentially reduce the occurrence of hip fractures in postmenopausal women diagnosed with osteoporosis. The hip bone strength may increase, decrease or remain at the same level during this study. The risk of hip fracture may also increase, decrease or remain at the same level. Study participation may not give direct benefits but may also benefit patients with osteoporosis in the future.

Contacts

Public
AgNovos Healthcare USA, LLC

Suite 100 7301 Calhoun Pl,
Rockville MD 20855
US
Scientific
AgNovos Healthcare USA, LLC

Suite 100 7301 Calhoun Pl,
Rockville MD 20855
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Subject is postmenopausal female (at least 1-year post menses)
2. Subject has osteoporosis as defined by a documented DXA scan T-score of <=

-2.5 in the femoral neck of at least one hip within the last year. If no documented T-score, then a DXA scan will be performed during eligibility screening.
3. Subject has 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 six (6) months removed from having a hip fracture repair or prosthesis, or less than three (3) months removed from an elective THA.
2. Subject has progressive increase in undiagnosed hip pain over the previous six months that in the opinion of the Investigator may suggest other underlying bone or joint pathology (e.g. rheumatoid arthritis, fracture, etc.).
3. Subject is dependent on the use of a wheel-chair or is bed-ridden.
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 insulin-dependent diabetes mellitus (IDDM).
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 exhibits excessive alcohol consumption as determined by the principal investigator*.
10. Subject has radiological evidence of gross bony or joint pathology, including signs predictive of atypical femoral fractures (e.g. Cortical beaking) or has been diagnosed and/or treated for atypical femoral fractures.
11. Subject treated with corticosteroids or systemic glucocorticoids for ten (10) days in the previous six (6) months.
12. Subject has history of oral or parenteral use of immune-suppressive drugs in the previous twelve months.
13. Subject has history of metabolic bone disease other than osteoporosis (ex. Paget*s disease).
14. Subject has a history of auto-immune arthritic diseases including rheumatoid, psoriatic, or those associated with systemic lupus erythematosus, spondyloarthropathy, Reiter*s Syndrome or Crohn*s Disease.
15. Subject has a history of radiation therapy to the hip or pelvic region.
16. Subject has a history of any invasive malignancy (except basal cell carcinoma), unless treated and with no clinical signs of symptoms of malignancy

for five (5) years.
17. Subject has known allergies to implanted device.
18. Subject has severe comorbidity or poor general physical/mental health that, in the opinion of the Investigator, will not allow the subject to be a good study candidate.
19. 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:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-04-2018
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	OSSURE (generic name AGN1) LOEP-Kit
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	23-08-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	27-08-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NCT02916953
CCMO	NL60420.068.17