Shelf acetabuloplasty with 3D printed implants as new treatment for symptomatic adult hip dysplasia.

Published: 13-05-2025
Last updated: 28-06-2025

A first in human study with a safety analysis and an evaluation of early performance in terms of the clinical outcomes after implantation of the 3D-Shelf implant in patients with adult hip dysplasia, to show that the 3D-Shelf procedure is safe, has...

Ethical review	Approved WMO
Status	Pending
Health condition type	Congenital and hereditary disorders NEC
Study type	Interventional

Summary

ID

NL-OMON57461

Source
ToetsingOnline

Brief title
AthenaTrial

Condition

- Congenital and hereditary disorders NEC
- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Acetabular dysplasia, underdeveloped hip joint

Research involving
Human

Sponsors and support

Primary sponsor: Replasia B.V.

Source(s) of monetary or material Support: Replasia B.V. deels bekostigd door een VLAIO beurs

Intervention

Keyword: 3 dimensional, 3D printing, hip dysplasia, Shelf acetabuloplasty

Outcome measures

Primary outcome

The primary study objectives are an evaluation of the safety, feasibility and the performance after implantation of the 3D-Shelf implant.

The safety will be evaluated by incidence, nature, and severity of procedure- and/or device-related adverse events up to 12 months post-surgery, with an interim analysis 6 months after the first 5 patients have undergone surgery. The clinical performance will be evaluated by describing the change from baseline in widely used questionnaires for the evaluation of osteoarthritis and/or hip surgeries, which cover aspects such as pain, range of motion (ROM), functioning in activities of daily life (ADL), gait, and quality of life.

Secondary outcome

The placement of the implant will be evaluated based on the accurate positioning of the implant and the technical feasibility of the surgery. Difficulties or deviations from the surgical protocol will be described. The implant positioning will be assessed by comparing the post-operative CT-scan to the pre-operative CT-scan and the planning of the implant.

To analyse potential predisposing risk factors for an unsuccessful outcome, the

clinical outcomes of the implantation of the 3D-Shelf will be correlated with

possible predisposing factors.

Study description

Background summary

Hip dysplasia is a common orthopedic condition, defined as a abnormality in the shape, size and orientation of the femoral head, acetabulum or both. The most frequent presentation of hip dysplasia is the maldevelopment of the acetabulum, resulting in insufficient superior coverage of the femoral head, defined as a lateral center-edge angle (Wiberg) of less than 20 degrees. Patients suffer from groin pain, an abnormal gait, decreased strength, and increased rate of degenerative hip disease.

The possible treatments affecting the shape of the acetabulum once the patient reaches adolescence, are all surgical. The PAO is regarded as the current gold standard in treatment of symptomatic adult hip dysplasia. The 3 dimensional orientation of the acetabulum is changed with the use of 3 osteotomies around the acetabulum and a refixation in the obtained position. However, the PAO is a difficult operation and is associated with a large number of major complications (up to 37%) and the surgery is associated with a long rehabilitation period.

Hence, a strong unmet need exists for an effective but less invasive solution that enhances the quality of life of the adult hip dysplasia patients. The treatment gap can be filled with a 3-dimensional (3D) shelf procedure (as mentioned by Willemsen et al). This custom made implant (called 3D-Shelf implant) was developed with the goal to be more predictable in terms of containment and fit than the old autologous shelf-acetabuloplasty, and less invasive and easier to perform than the PAO.

Study objective

A first in human study with a safety analysis and an evaluation of early performance in terms of the clinical outcomes after implantation of the 3D-Shelf implant in patients with adult hip dysplasia, to show that the 3D-Shelf procedure is safe, has lower complication rates and shows no inferiority in clinical-outcome compared to the current treatment of a peri-acetabular osteotomy.

Study design

Single centre, prospective, open-label, clinical investigation involving a new medical implant device, that will be performed at the Anna hospital in Geldrop. The study aims to assess the clinical outcomes and safety of the first in-human implantation of the 3D-Shelf implant.

Refer to the study protocol on pages 23-25 for a detailed description of the methodology.

Intervention

Prior to the surgery the patients will need a CT scan and a MRI scan to design the patient specific implant. The patients will be admitted to the hospital for implantation of the 3D-Shelf, and will stay for at least one night after surgery. For the first 6 weeks after surgery the patients will be limited to partial loadbearing on the treated hip, using crutches.

Study burden and risks

Replasia BV performed risk analysis in accordance with EN ISO 14971:2019.

Careful definitions of specific eligibility criteria, study procedures and instructions for use, appropriate selection, qualification and training of the investigators, and patient follow-up procedures have been designed as to further contribute to reduce risks as far as possible for the patient and residual risk acceptance. For this study the residual risks have been controlled to levels as low as possible.

For the purpose of risk control and mitigation during the conduct of the study the clinical investigation will be split into 2 phases:
• The Safety phase of the clinical investigation will enrol a small cohort of subjects within which the initial safety of the 3D-Shelf implant will be evaluated at an interim analysis at 6 months post surgery by the DSMB. A maximum of 5 subjects will be treated. A formal review of safety will be undertaken when all patients reach 12 months post-surgery.
• The Performance phase of the clinical investigation will enrol subjects until a total of 10 subjects have been treated with the investigational device.
Furthermore, potential risks associated with participation in this investigation will be minimized and managed in accordance with ISO 14155, and requirements of the approving Ethics Committee(s).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Hip dysplasia based on AP x-ray with a LCEA of <25°
• Groin pain and/or gait abnormalities, with no other explanatory hip pathology
• Aged at least 18 years and maximal 45 years at time of surgery (indicated age for PAO(19))
• Willing to comply with the study visit schedule during 12 month follow-up
• Able and willing to provide informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Previous acetabular surgery >10yr of age
• Signs of osteoarthritis on x-ray (Tonnis classification >1),
• Body mass index of more than 35

• Large labral tears visible on non-contrast MRI
• Pre-consultation known titanium allergy
• Pre-consultation known medical histories of diseases that per the investigator possibly affect the outcome: neuromuscular disease affecting the stability of the hip, diseases affecting bone ingrowth and fixation strength of the implant like rheumatoid arthritis and metabolic bone diseases, e.g. osteomalacie, osteoporosis, hyperparathyroidism, hypercalcemia.
• Pre-consultation known pregnant women or women who are planning to become pregnant during the duration of the study.
• Part of vulnerable population (e.g. Mentally disabled with cognitive impairment or mental disease)
• Currently participating in another investigational clinical trial.
• Unable to provide informed consent (e.g. insufficient language skills)

Study design

Design

Study type: Interventional

Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2025
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	3D-Shelf System
Registration:	No

Ethics review

Approved WMO Date:	08-05-2025
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-05-2025
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL80265.000.24