Safety, clinical performance and Survival of the Uncemented Glenoid Affinis Vitamys

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A post marketing surveillance study to assess safety, clinical performance and survival of the uncemented Glenoid Affinis vitamys Uncemented Glenoid Affinis Vitamys total prosthetic shoulder replacement. All implants already bear the CE-marking.

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

Summary

ID

NL-OMON57214

Source
ToetsingOnline

Brief title
SUGAVI study

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
shoulder arthoplasty, total shoulder replacement

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: Mathys medical,Mathys Medical Ltd

Intervention

Keyword: arthroplasty, post marketing surveillance study, shoulder

Outcome measures

Primary outcome

The primary endpoint of the study is the survival RLL score according to Molé

at five years of the Uncemented uncemented Glenoid Affinis Vitamysvitamys.

Secondary outcome

The secondary endpoints of the study are the clinical outcomes and performance

of the Uncemented Glenoid Affinis Vitamys, complication rate after surgery, and

patients reported outcome measures (PROMS) pre-operative as well as

post-surgery. The final endpoint is the product survival rate of the

Uncemented Glenoid Affinis Vitamys at ten years.

Study description

Background summary

Glenoid component loosening is still one of the major problems in shoulder arthroplasty. Multiple factors including the method of glenoid preparation, cementing technique, implant-material etc. are considered potential reasons for loosening within the cement-bone interface. Cementless fixation for arthroplasty is not a new concept and has been used in the hip and the knee for many years. However, experience with cementless fixation for shoulder arthroplasty remains small especially for a primary monoblock glenoid component. The vitamys (vitamin E blended highly cross-linked polyethylene) material used for the Affinis Glenoid vitamys uncemented components has been in clinical use since 2009. The first application was a monoblock cup implant (RM pressfit vitamys) which is used for total hip arthroplasty.

Study objective

A post marketing surveillance study to assess safety, clinical performance and survival of the uncemented Glenoid Affinis vitamys Uncemented Glenoid Affinis

Vitamys total prosthetic shoulder replacement. All implants already bear the CE-marking.

Study design

Open-label Single-arm prospective observational multicentre study

Study burden and risks

Patients can choose whether to participate in the study and receive the uncemented Glenoid Affinis vitamysaffinis glenoid vitamys uncemented. Alternative option is the total shoulder arthroplasty performed as standard of care in the sites. In addition to the benefits from the TSA surgery e.g. reduced pain, improved range of motion, patients might benefit from the type ofuncemented shoulder prosthesis that will be used in this study in terms of the shorter surgery time and reduced damage in case of revision associated with uncemented arthroplasty in general. There is minimal risk associated with participating in this study over and above that of the primary shoulder arthroplasty procedure. All devices are CE marked and will be used according to its labelling. Data collection involves usual care after the surgery, namely questionnaires (PROMs), radiographs and range of motion, with an additional radiographic evaluation at 2 years follow-up.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Primary TSA implantation
Primary osteoarthritis, secondary osteoarthritis, fracture sequelae, avascular necrosis of the humeral head
Age at inclusion >18 years
Intact rotator cuff
Glenoid retroversion <15% and <70% humeral head subluxation (Walch type A1, A2, B1, B2 glenoid)

Exclusion criteria

Missing consent
Rheumatoid athritis
Known or suspected non-compliance (e.g. drug or alcohol abuse)
Revision surgery
Presence of sepsis or malignant tumours
Chemotherapy treatment within 6 months before surgery
>5mg/day of corticosteroids, excluding inhalers, within 3 months before surgery
Women who are pregnant or breast feeding
Glenoid retroversion >15% (Walch type C glenoid)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2025
Enrollment:	73
Type:	Anticipated

Medical products/devices used

Generic name:	Uncemented Glenoid Affinis Vitamys total prosthetic shoulder
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	08-01-2025
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	NL79929.100.22