# 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

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#### 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**

#### **Public**

Amphia Ziekenhuis

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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** CCMO

ID

NL79929.100.22