Trial Description

Title

A prospective PMCF multicentre study analysing performance and safety outcome of the Affinis Glenoid vitamys uncemented in total shoulder arthroplasty

Trial Acronym

[---]*

URL of the trial

http://-

Brief Summary in Lay Language

The Affinis Glenoid vitamys uncemented is used in total shoulder arthroplasty to treat diseased shoulder joints.

Mid- to long-term safety and performance of the Affinis Glenoid vitamys uncemented shall be investigated

Brief Summary in Scientific Language

A prospective PMCF multicentre study analysing performance and safety outcome of the Affinis Glenoid vitamys uncemented in total shoulder arthroplasty

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00017483**
- Date of Registration in DRKS: **2019/07/26**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **68/19 , Ethikkommission der Medizinischen Fakultät der Otto-von-Guericke-Universität Magdeburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **M19.0 - Primary arthrosis of other joints**
- ICD10: **M19.1 - Post-traumatic arthrosis of other joints**
- ICD10: **M19.2 - Other secondary arthrosis**

Interventions/Observational Groups

- Arm 1: **Single-arm prospective observational multicentre study of the Affinis Glenoid vitamys. Clinical and radiological follow-ups are taking place after 6 weeks, 6, 12, 24 Months and 5, 7 and 10 years.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The primary endpoint of the study is the assessment of the radiolucent lines of the Affinis Glenoid vitamys uncemented at two years after surgery. Clinical and radiological examination with two radiographs (anterior-posterior and axial view)

Secondary Outcome

The secondary endpoints of the study are the clinical outcomes and complications at two years after surgery.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Otto-von-Guericke-Universität, Magdeburg**
- Medical Center **Sporthopaedicum Straubing, Straubing**
- Medical Center **HELIOS Park-Klinikum Leipzig, Leipzig**
- Medical Center **OCC Tübingen, Tübingen**
- Medical Center **Marienstift Arnstadt, Arnstadt**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/01/16**
- Target Sample Size: **75**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

-Informed consent form (signed by participant and investigator)
- Primary implantation
- Primary osteoarthritis, secondary osteoarthritis, fracture sequelae, avascular necrosis of the humeral head
- Age at inclusion >18 years
- Intact rotator cuff
- Preoperative Constant Score >20 points
- Glenoid <15° retroversion and <70% humeral head subluxation

Exclusion criteria

-Missing consent
- Rheumatoid arthritis
- 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

Addresses

■ **Primary Sponsor**

Mathys AG Bettlach
Ms. N/A Marlen Egger
Robert Mathys Strasse 5
2544 Bettlach
Switzerland

Telephone: **+41 32 644 1429**
Fax: **N/A**
E-mail: **Marlen.Egger at mathysmedical.com**
URL: **www.mathysmedical.com**

■ **Contact for Scientific Queries**

Otto-von-Guericke-Universität
Mr. Dr. Alexander Berth
Leipziger Strasse 44
39120 Magdeburg
Germany

Telephone: **+49 391 671 4034**
Fax: **N/A**
E-mail: **alexander.berth at med.ovgu.de**
URL: **N/A**

■ **Contact for Public Queries**

Mathys Orthopädie GmbH
Ms. Natividad Zeleny
Seilfahrt 99
44809 Bochum
Germany

Telephone: **+49 170 572 2702**
Fax: **[---]***
E-mail: **natividad.zeleny at mathysmedical.com**
URL: **[---]***

Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Commercial (pharmaceutical industry, medical engineering industry, etc.)

Mathys AG Bettlach
Ms. Marion Röthlisberger
Robert Mathys Strasse 5
2544 Bettlach
Switzerland

Telephone: **+41 32 644 15 26**
Fax: **[---]***
E-mail: **marion.roethlisberger at mathysmedical.com**
URL: **http://www.mathysmedical.com**

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*