PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

German speaking Arthroscopy Registry

Trial Acronym

DART

URL of the trial

http://www.arthroskopieregister.de/

Brief Summary in Lay Language

The German speaking Arthroscopy Registry is a web-based platform for quality management and outcome research in the field of minimal invasive joint surgery. To fulfill the aims of the registry patients will be provided with outcome questionnaires 6, 12, 24, 36, 52 and 120 after surgery via email links.

Brief Summary in Scientific Language

The German speaking Arthroscopy Registry is a web-based platform for quality management and outcome research in the field of arthroscopic joint surgery. To fulfill the aims of the registry patients will be provided with outcome questionnaires 6, 12, 24, 36, 52 and 120 after surgery via email links. These questionnaires include validated functional scores, activity scores and QOL scores. Surgeons will describe the individual pathology, process of surgery and perioperative management by a questionnaire.

Organizational Data

- DRKS-ID: **DRKS00012994**
- Date of Registration in DRKS: **2018/01/09**
- 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.: **Eth-26/17 , Ethik-Kommission der Ärztekammer Berlin**

Secondary IDs

Health condition or Problem studied

- ICD10: **S40-S49 - Injuries to the shoulder and upper arm**
- ICD10: **S50-S59 - Injuries to the elbow and forearm**
- ICD10: **S60-S69 - Injuries to the wrist and hand**
- ICD10: **S70-S79 - Injuries to the hip and thigh**
- ICD10: **S80-S89 - Injuries to the knee and lower leg**
- ICD10: **S90-S99 - Injuries to the ankle and foot**
- ICD10: **T00-T07 - Injuries involving multiple body regions**
- ICD10: **T80-T88 - Complications of surgical and medical care, not elsewhere classified**
- ICD10: **M00-M25 - Arthropathies**
- ICD10: **M80-M94 - Osteopathies and chondropathies**
- ICD10: **M95-M99 - Other disorders of the musculoskeletal system and connective tissue**

Interventions/Observational Groups

- Arm 1: **The arthroscopic procedure will be performed as part of the routine management. Suitable patients will be informed by the surgeon. After the patient has given informed consent medical data will be provided by the patient via questionnaires 6, 12, 24, 36, 60 and 120 months after surgery. The time to answer each questionnaire will be approximately 15-20 minutes. Each study site can choose from two ways of data input: quality management (basic) and health care science (science). Since quality management primarily aims for internal quality issues or communication with health care authorities no ethical approval is needed. However the patients need to sign the patient informed consent, mainly for data protection reasons. Data from the quality management tool will not be used for scientific publication. In contrast, each site which enters data into the science part needs an ethical approval.**

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**

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: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary outcome knee: Therapy response defined as reduction of 8 or more points in the KOOS (knee injury and osteoarthritis outcome score) after 24 months.
Primary outcome hip joint: iHot 12 (International Hip Outcome Tool, short version) after 24 months
Primary outcome ankle joint: Therapy response defined as reduction of 8 or more points in FAAM (Foot and Ankle Ability Measure) after 24 months.
Primary outcome shoulder: Therapy response defined as reduction of 12 or more points in American Shoulder and Elbow Surgeon's Standardized Shoulder Assessment Form (ASES) for RM rupture and 9 points or more for prostheses.

Secondary Outcome

Secondary outcomes knee: KOOS after 6, 12, 36, 60 and 120 months, VAS (Visual Analogue Scale) after 6, 12, 24, 36, 60 and 120 months, EQ5D (health-related quality of life questionnaire) after 6, 12, 24, 36, 60 and 120 months, Marx Score (Marx Activity Rating Scale) after 6, 12, 36, 60 and 120 months
Secondary outcomes hip joint: iHot 12 after 6, 12, 36, 60 and 120 months, VAS after 6, 12, 24, 36, 60 and 120 months, EQ5D after 6, 12, 24, 36, 60 and 120 months, Marx score after 6, 12, 36, 60 and 120 months.
Secondary outcomes ankle joint: FAAM after 6, 12, 36, 60 and 120 months, VAS after 6, 12, 24, 36, 60 and 120 months, EQ5D after 6, 12, 24, 36, 60 and 120 months, Marx score after 6, 12, 36, 60 and 120 months.
Secondary outcomes shoulder: Oxford Shoulder Score or ASES after 6, 12, 36, 60 and 120 months, VAS after 6, 12, 24, 36, 60 and 120 months, EQ5D after 6, 12, 24, 36, 60 and 120 months, Marx Score after 6, 12, 36, 60 and 120 months

Countries of recruitment

- DE **Germany**
- CH **Switzerland**
- AT **Austria**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/11/09**
- Target Sample Size: **5000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

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

Additional Inclusion Criteria

- Male and female patients aged ≥ 18 years
- Patients with arthroscopic joint surgery of the knee, hip, ankle or shoulder
- Patients who give their written informed consent
- Patients who are able to understand the nature, significance and consequences of the trial
- Patients with a valid e-mailaddress

Exclusion criteria

No exclusion criteria specified

Addresses

- **Primary Sponsor**

  Deutschsprachiges Arthroskopieregister gGmbH (DART gGmbH)
  Breite Straße 96
  41460 Neuss
  Germany

  Telephone: **[---]***
  Fax: **[---]***

Primary Sponsor

Deutschsprachiges Arthroskopieregister gGmbH (DART gGmbH)
Breite Straße 96
41460 Neuss
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Deutschsprachiges Arthroskopieregister gGmbH (DART gGmbH)
Mr. Priv.-Doz. Dr. med. Ralf Müller-Rath
Breite Straße 96
41460 Neuss
Germany

Telephone: **+49 2131 51 257 22**
Fax: **[---]***
E-mail: **office at arthroskopieregister.de**
URL: **[---]***

■ **Contact for Public Queries**

Deutschsprachiges Arthroskopieregister gGmbH (DART gGmbH)
Mr. Priv.-Doz. Dr. med. Ralf Müller-Rath
Breite Straße 96
41460 Neuss
Germany

Telephone: **+49 2131 51 257 22**
Fax: **[---]***
E-mail: **office at arthroskopieregister.de**
URL: **[---]***

Sources of Monetary or Material Support

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

AGA - Gesellschaft für Arthroskopie und Gelenkchirurgie (Deutschsprachige Arbeitsgemeinschaft für Arthroskopie)
1090 Wien
Austria

Telephone: **[---]***

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

AGA - Gesellschaft für Arthroskopie und Gelenkchirurgie (Deutschsprachige Arbeitsgemeinschaft für Arthroskopie)
1090 Wien
Austria

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

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

Berufsverband für Arthroskopie e.V.
41460 Neuss
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

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

GOTS - Gesellschaft für Orthopädisch-Traumatologische Sportmedizin
07749 Jena
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

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

DGOU - Deutsche Gesellschaft für Orthopädie und Unfallchirurgie
10623 Berlin
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

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

Arthrex GmbH
81249 München

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

Arthrex GmbH
81249 München
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

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

Smith & Nephew GmbH
22763 Hamburg
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

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

medi GmbH & Co. KG
95448 Bayreuth
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

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

Juzo - Julius Zorn GmbH
86551 Aichach
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

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

DJO Global - ORMED GmbH
79100 Freiburg
Germany

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

DJO Global - ORMED GmbH
79100 Freiburg
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

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

DIZG - Deutsches Institut für Zell- und GewebeersatzGemeinnützige Gesellschaft mbH
12555 Berlin
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

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

OPED GmbH
83626 Valley
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

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.*