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

Trial Description

Title

ROUTE registry

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Observational registry documenting the use of the Edwards SAPIEN XT transcetheter heart valve delivered via an aortic Access using the Ascendra+ delivery System.

Brief Summary in Scientific Language

The purpose of this registry is to expand upon existing data sets, to identify patient characteristics and indicators related to complications and clinical benefits for patients with symptomatic severe calcific degenerative aortic stenosis that are undergoing transaortic transcatheter procedure with the commercially available Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ System.

Organizational Data

- DRKS-ID: **DRKS00005294**
- Date of Registration in DRKS: **2013/11/07**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **5846/13 , Ethik-Kommission der Fakultät für Medizin der Technischen Universität München**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1149-9900**

Health condition or Problem studied

- MedDRA: **10002918 (Aortic valve stenosis)**
- MedDRA: **10050559 (Aortic valve calcification)**
- ICD10: **I35.0 - Aortic (valve) stenosis**

Interventions/Observational Groups

- Arm 1: **All Patients undergoing transaortic transcatheter valve implantation with commercially available Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery-System.**

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

Primary Outcome

Overall mortality within 30d after TAVI.

Secondary Outcome

- TAVI related in-hospital and 30d mortality
- Complication rates as to VARC2 (Valve Academic Research Consortium-2)
- Identify multivariable adjusted predictors for adverse outcomes of transaortic TAVI
- Further establish role of CT-technology in patient screening (valve sizing, complication prevention)

Countries of recruitment

- DE **Germany**
-

FI **Finland**

- FR **France**
- IT **Italy**
- NL **Netherlands**
- UK **United Kingdom**
- PL **Poland**
- AT **Austria**
- DK **Denmark**
- NO **Norway**

Locations of Recruitment

- Medical Center **Policlinico San Matteo/Department of Cardiac Surgery, Pavia**
- University Medical Center **Academisch Medisch Centrum, Amsterdam**
- Medical Center **St. Thomas Hospital Cardiothoracic surgery dept., London**
- Medical Center **James Cook Hospital - Cardiothoracic Division - , Middlesborough**
- Medical Center **Hopital Cardio-Vasculaire et Pneumologie Louis Pradel, Lyon**
- University Medical Center **Klinika Kardiochirurgii UCK Gdansk, Gdansk**
- University Medical Center **Division of Cardiology, Helsinki University Central Hospital, Helsinki**
- University Medical Center **Rikshospital Oslo, Oslo**
- Medical Center **Städt. Klinikum München GmbH Herzchirurgie Bogenhausen, München**
- University Medical Center **Herzzentrum Leipzig GmbH - Universitätsklinik - , Leipzig**
- Medical Center **Robert-Bosch-Hospital, Stuttgart, Stuttgart**
- University Medical Center **Uksh Kiel, Dep. Of Cardiology u. Angiology, Kiel**
- University Medical Center **Westdeutsches Herzzentrum Essen - Uniklinikum - , Essen**
- University Medical Center **Cardiac Surgery dpt., Innsbruck Medical University Hospital, Innsbruck**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/03/07**
- Target Sample Size: **200**
- 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

- Intended transaortic (Tao) TAVI using Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery-System
- Compliance with the indications according to the Instructions for Use (Appendix 12.1)
- Written informed consent

Exclusion criteria

- Presence of contraindications as to the Instructions for Use
- TAo with concomitant procedure (e.g. Tao + CABG)
- Participation in the SOURCE XT registry
Data collection and follow-up
Patient data are collected at valve implantation

Addresses

- **Primary Sponsor**

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  Germany

  Telephone: **+49 4471 850 3331**
  Fax: **+49 4471 850 3332**
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  URL: **www.route-registry.com**

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-

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E-mail: **kp at route-registry.com**
URL: **[---]***

Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

IPPMed GmbH
Osterstr. 15
49661 Cloppenburg
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.*