PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Deutsches Dual Therapy Stent Register

Trial Acronym

DTS Register

URL of the trial

[---]*

Brief Summary in Lay Language

The DTS.DE registry is an initiative for the collection of high quality process and historical data of implantations with the COMBO Dual Therapy Stent in Germany. DTS.DE was designed as a national, non- randomized, prospective, multicenter registry without a comparison group.

The responsible Steering Committee is of the opinion that the Combo stent qualifies for further documentation of treatment results in the form of a German registry, based the CE certification of the COMBO Dual Therapy stent in 2013 and its clinical and scientific investigation in the context of the REMEDEE study program, as well as company independent externally initiated studies with the COMBO Dual Therapy Stent.

It is expected that by mid- 2015, at least 1,000 patients will be enrolled and documented in the DTS.DE registry with the COMBO Dual Therapy Stent. A clinical follow-up is performed after 6 weeks and 12 months.

Brief Summary in Scientific Language

It is the objective of the DTS.DE registry to capture the documentation of all patients who have been treated with a Combo Dual Therapy Stent in Germany, and who have been properly informed and consented with regards to their participation in the registry. All of these

patients will be registered in the electronic data capturing system (eCRF) of the DTS.DE registry and will be followed and documented for a period of 12 months.

Organizational Data

- DRKS-ID: **DRKS00007244**
- Date of Registration in DRKS: **2015/04/24**
- Date of Registration in Partner Registry or other Primary Registry: **2014/03/24**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT02102997 (ClinicalTrials.gov)**
- Sponsor-ID: **DTS.DE Register V 1.2 (OrbusNeich)**

Health condition or Problem studied

- Free text: **Coronary Artery Disease**
- ICD10: **I20-I25 - Ischaemic heart diseases**

Interventions/Observational Groups

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **[---]***
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **[---]***
- Purpose: **[---]***
- Assignment: **[---]***
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Study Type: **Non-interventional**

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Allocation: **[---]***

Blinding: **[---]***

Who is blinded: **[---]***

Control: **[---]***

Purpose: **[---]***

Assignment: **[---]***

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Target Vessel Failure (TVF); time frame: 12 months; TVF is defined as the hierarchical composite of target vessel related Major Adverse Cardiac Events (MACE). MACE is defined as the composite of death, myocardial infarction and target lesion revascularization (TLR).

Secondary Outcome

- Procedural success; time frame: Day of procedure; Successful implantation of the stent and a residual stenosis of less than 20%
- MACE; time frame: 6 weeks and 12 months; MACE is defined as the composite of of death, myocardial infarction and target lesion revascularization
- Stent induced serious adverse events (SAE); time frame: 12 months
- Stent thrombosis; time frame: 12 months; Classified per ARC definitions as definite, probable or possible stent thrombosis
- Thrombolysis in Myocardial Infarction (TIMI) bleeding; time frame: 12 months; Bleeding as defined by the TIMI criteria: major, minor or minimal

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Kardiologie Lukaskrankenhaus Neuss, Neuss**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2013/07/31**
- Target Sample Size: **1000**
- Monocenter/Multicenter trial: **[---]***
- National/International: **[---]***

Inclusion Criteria

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

Additional Inclusion Criteria

- Patients has at least one coronary lesion, suitable for PCI treatment with the Combo stent in accordance with European Society of Cardiology Guidelines and local Guidelines of the Deutsche Gesellschaft für Kardiologie for drug eluting stents

Exclusion criteria

- Patient has previously received murine therapeutic antibodies and exhibited sensitization through the production of Human Anti- Murine Antibodies (HAMA)

- Patient in whom anti-platelet and/or anticoagulant therapy is contraindicated

- Patient in whom a complete inflation of the angioplasty balloon or correct stent placement is thought to be inhibited

Addresses

- **Primary Sponsor**

  OrbusNeich

Primary Sponsor

OrbusNeich

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
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- **Contact for Scientific Queries**

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- **Contact for Public Queries**

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Telephone: **+49 6202 127360**
Fax: **[---]***
E-mail: **erdmann.zippel at aptivsolutions.com**
URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

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

Status

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

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.

- Translation on version: 1

- Last processed date by ClinicalTrials.gov: 2014/11/05

** 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.*