

Triple therapy following implantation of everolimus drug-eluting stent in patients with prior phenprocoumon treatment

Submission date 20/01/2017	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 24/03/2017	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 24/03/2017	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Atrial fibrillation is a condition where the heart rate is irregular and often abnormally fast. This increases the risk of blood clots forming in the heart chambers, which can enter the bloodstream and cause a stroke. Patients are therefore prescribed anticoagulant medicines to prevent blood clots. These patients are often implanted with a short wire-mesh tube, called a stent, into their coronary (heart) arteries. After that, they need an antithrombotic medication that reduces the formation of blood clots in order to keep the stent open. This combination of medications causes a high risk of bleeding, but is necessary to prevent both strokes and stent clotting. Therefore, modern stents are implanted that allow a very short time period of this combined medication. The best time period for this combination is unclear. The aim of this study is to assess the risks and the benefits of a short period of combination treatment in patients after implantation of a specific coronary stent (Xience).

Who can participate?

Patients aged over 18 with coronary artery disease, treated with stent implantation at Münster University Hospital, who require anticoagulant medication due to atrial fibrillation

What does the study involve?

All participants are contacted once in the follow-up period. Adverse events (side effects) due to both bleeding and thromboembolic (blood clotting) reasons are recorded, including death, myocardial infarction (heart attack), stent clotting, stroke, and major bleeding. The participants' intake of medication is also recorded.

What are the possible benefits and risks of participating?

The results may help determine the best duration of treatment in the future. There are no risks for the participants because the treatment is standard of care according to guidelines.

Where is the study run from?

University Hospital Münster (Germany)

When is the study starting and how long is it expected to run for?

June 2015 to December 2016

Who is funding the study?

University Hospital Münster (Germany)

Who is the main contact?

Dr Dieter Fischer

Contact information

Type(s)

Scientific

Contact name

Dr Dieter Fischer

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Contact details

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Additional identifiers

Protocol serial number

DAPT-Triple

Study information

Scientific Title

Triple therapy following implantation of everolimus drug-eluting stent in patients with prior phenprocoumon treatment: a retrospective observational study

Study objectives

To evaluate the safety and efficacy of a modified anticoagulation strategy in this specific patient cohort after everolimus DES Implantation and prior anticoagulation therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethik-Kommission der Ärztekammer Westfalen-Lippe und der Westfälischen Wilhelms-Universität, 04/05/2015, ref: 2015-203-f-S

Primary study design

Observational

Study design

Retrospective observational study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Coronary artery disease, atrial fibrillation

Interventions

All patients will be contacted once in the follow-up period. Adverse events for both bleeding and thromboembolic reasons will be analysed (death, myocardial infarction, stent thrombosis, stroke, major bleeding). Furthermore, the intake of medication (duration) will be recorded.

Intervention Type

Device

Primary outcome(s)

1. Safety of triple therapy, measured using a standardized questionnaire at a single follow-up timepoint
2. Efficacy of triple therapy, measured using a standardized questionnaire at a single follow-up timepoint

Key secondary outcome(s)

Risk factors for events (bleeding or thrombotic), measured using a standardized questionnaire at a single follow-up timepoint

Completion date

31/12/2016

Eligibility

Key inclusion criteria

1. Patients with coronary artery disease
2. Treated with drug-eluting stent implantation at Münster University Hospital
3. Indication for oral anticoagulation due to atrial fibrillation
4. Age > 18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Age < 18 years
2. Current pregnancy
3. Underlying malignant disease
4. Previous stent thrombosis
5. Active bleeding
6. Other OAC indications than atrial fibrillation (e.g. pulmonary embolism, mechanical valves)
7. Patients who were unable to give informed consent

Date of first enrolment

01/06/2015

Date of final enrolment

31/12/2016

Locations

Countries of recruitment

Germany

Study participating centre

University Hospital Münster

Department of Cardiovascular Medicine

Münster

Germany

48149

Sponsor information

Organisation

University Hospital Münster

ROR

<https://ror.org/01856cw59>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital Münster

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Dieter Fischer.

IPD sharing plan summary

Available on request