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

Submission date
20/01/2017

Registration date
24/03/2017

Last Edited
24/03/2017

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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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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

Study design

Retrospective observational study

Primary study design
Observational

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