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Short antithrombotic therapy after stent implantation in high bleeding risk patients

Submission date
28/11/2018

Recruitment status
No longer recruiting

Registration date
18/12/2018

Overall study status
Completed

Last Edited
27/09/2021

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
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. Many patients are at high risk of bleeding, but is necessary to prevent stent clotting, which is difficult in daily practice. 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 (Biofreedom) in high bleeding risk patients.

Who can participate?
Patients aged over 18 with coronary artery disease, treated with stent implantation at Münster University Hospital, who are at high risk for bleeding

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?
July 2015 to February 2019

Who is funding the study?
University Hospital Münster (Germany)

Who is the main contact?
Dr Dieter Fischer
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DAPT_DF

Study information

Scientific Title
Implantation Of Biofreedom® drug-coated stents with very short dual antiplatelet therapy In patients at high bleeding risk: real-world data

Acronym
Biofreedom short DAPT

Study objectives
Patients at high risk of bleeding requiring percutaneous coronary intervention (PCI) are a challenging group who need careful evaluation of both their thrombotic and bleeding risks. Deciding on duration and intensity of antithrombotic management is difficult and has to be well balanced. In these patients, a polymer-free metallic stent coated with biolimus-A9 (Biofreedom®) followed by a one-month dual antiplatelet therapy has shown to be safer and more effective when compared to a bare metal stent during a two year follow-up (LEADERS-free trial). Yet, data on safety and efficacy outside a trial are scare. Therefore, the trialists analyzed this regimen in a real-world scenario.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the University of Muenster (Germany) and the Aerztekammer Westfalen-Lippe (Muenster, Germany), 05/10/2016, ref: 2016-487-f-S

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Patients with coronary artery disease and indication for PCI

Interventions
Short antiplatelet therapy after implantation of the Biofreedom DE-stent in a real world scenario

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
Mixed

Primary outcome measure
1. Safety of a short antithrombotic therapy after stent implantation, measured using a standardized questionnaire at a single follow-up timepoint
2. Efficacy of short antithrombotic therapy, measured using a standardized questionnaire at a single follow-up timepoint

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

Overall study start date
01/07/2015

Completion date

01/02/2019

Eligibility

Key inclusion criteria
1. Implantation of at least one Biofreedom® stent for the treatment of significant CAD during the study period
2. At least one criterion for high risk bleeding

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Total final enrolment
89

Key exclusion criteria
1. Aged <18 years
2. Current pregnancy
3. Underlying malignant disease
4. Active bleeding
5. Unable to give informed consent

Date of first enrolment
01/10/2015

Date of final enrolment
01/11/2016

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital, Dept. Cardiology
Albert-Schweitzer-Campus 1, Geb. A1
Münster
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48143

Sponsor information

Organisation
University Hospital of Muenster

Sponsor details
Albert-Schweitzer-Campus 1, Geb. A1
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Sponsor type
University/education

ROR
https://ror.org/01856cw59

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
1. Abstract at the CRT Congress in Washington DC 2017
2. Publication in a cardiology journal in English

Intention to publish date
01/02/2019

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 (dieterfischer@yahoo.de). Data will be stored in the study department (computer and paper, e.g. informed consents). Access to data is possible 24/7 for authorized personnel and also for official inspections. Study data will be stored at least for 15 years. All data is anonymized, the written informed consents are also stored in the study department of the clinic. There are no legal restrictions.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/01/2020	27/09/2021	Yes	No