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Long-term outcomes for heart attack patients treated with a naturally-dissolving blood vessel support

Submission date
04/06/2019

Recruitment status
No longer recruiting

Registration date
07/06/2019

Overall study status
Completed

Last Edited
20/01/2022

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
A bioresorbable scaffold (BRS) can hypothetically decrease the risk of an adverse cardiac event in the long-term perspective. The BRS is a device which is inserted into a blood vessel in order to expand the vessel to prevent or alleviate a blockage, manufactured from a material that may dissolve or be absorbed in the body. The of the study is to assess the long-term outcomes of using a BRS for the urgent treatment of coronary artery block.

Who can participate?
Patients undergoing surgery for STEMI type heart attack.

What does the study involve?
Patients undergoing urgent surgery for a STEMI type heart attack will be treated using the BRS and followed up over 5-years during their regular appointments.

What are the possible benefits and risks of participating?
An improved long-term outcome with normal vessel anatomy (no vessel metallic cage as the device is resorbed over time).
Higher risk of scaffold late thrombosis.

Where is the study run from?
1. University Hospital Kralovske Vinohrady third medical faculty, Charles University, Czechia
2. Military hospital Prague, Czechia

When is the study starting and how long is it expected to run for?
December 2012 to December 2020

Who is funding the study?
Univerzita Karlova v Praze (Charles University, Prague), Czechia

Who is the main contact?
Dr Petr Tousek,
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Bioresorbable scaffold implantation in STEMI patients

Acronym
PRAGUE-19

Study objectives
Good longterm clinical outcome after bioresorbable scaffold (BRS) implantation, complete scaffold resorbtion at 5 year with stable lumen patency

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 09/01/2013, Local and multicenter ethical committee of the University Hospital Kralovske Vinohrady (Srobatrova 50, Prague 10, eticka.komise@fnkv.cz, +420267162272), ref: EK-VP/02/2013
2. Amendment approved 03/10/2018, ref: EK-VP/02/4/2013

Study design
Prospective two-centre open-label registry study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Acute myocardial infarction with ST segment elevation

Interventions
Use of bioresorbable scaffold (AbsorbTM BRS) during primary coronary intervention.
Patients enrolled in this study were treated during primary percutaneous coronary intervention (PCI) with the bioresorbable scaffold implantation (in some of the patients, optical coherence tomography (OCT) was performed just after BRS was implanted - if clinically possible).
Patients are followed by clinical and phone controls during 5 years.
First 25 eligible patients that agreed with the contol invasive imaging underwent 5 year coronary angiography and OCT.

Intervention Type
Device

Phase
Phase IV

Primary outcome measure
At 5 years:
1. Death using patient records
2. MI using patient records
3. Target vessel revascularization as recorded in records by a specialist

Secondary outcome measures
Vessel invasive assessment using QCA and optical coherence tomography at baseline and 5 years.

Overall study start date
01/12/2012

Completion date
15/12/2020

Eligibility

Key inclusion criteria
1. STEMI patients
2. Sign informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
130

Total final enrolment
117

Key exclusion criteria
1. Severe calcification
2. Do not meet specified vessel size
3. Length of the lesion more than 28mm
4. Indication for anticoagulation, cardiogenic shock

Date of first enrolment
15/12/2012

Date of final enrolment
15/12/2015

Locations

Countries of recruitment
Czech Republic

Study participating centre
University Hospital Kralovske Vinohrady third medical faculty, Charles university
Srobarova 50
Prague
Czech Republic
10034

Study participating centre
Military hospital Prague
U Vojenské nemocnice 1200
Prague
Czech Republic
16902

Sponsor information

Organisation
Charles University, University Research programme UNCE 02 and PROGRES Q38

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Sponsor type
University/education

Website
www.cuni.cz

ROR
https://ror.org/024d6js02

Funder(s)

Funder type
University/education

Funder Name

Univerzita Karlova v Praze

Alternative Name(s)
Charles University, Charles University in Prague, Univerzita Karlova, Karls-Universität zu Prag, UK

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Czech Republic

Results and Publications

Publication and dissemination plan
Pilot study published in 2014, 2-year interim analysis published in 2016, imaging analysis planned to published in 2019, final results in 2020.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to ethical restrictions on data sharing.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	interim analysis	17/05/2016	05/06/2019	Yes	No
Other publications	pilot study	01/03/2014	05/06/2019	Yes	No
Results article		30/01/2020	03/02/2020	Yes	No