ISRCTN89434356 https://doi.org/10.1186/ISRCTN89434356

The effectiveness of new bioresorbable coronary stents in the treatment of patients with acute coronary syndromes

Submission date
09/05/2021

Recruitment status
No longer recruiting

Registration date
12/05/2021

Overall study status
Completed

Last Edited
13/09/2021

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Acute coronary syndromes are a range of conditions associated with suddenly reduced blood flow to the heart. They can be treated with percutaneous coronary intervention (PCI), where a tube-shaped device called a coronary stent is placed in the coronary arteries that supply blood to the heart to keep them open. There is little evidence about the effectiveness and safety of magnesium-based bioresorbable (naturally-dissolving) coronary stents in patients with acute coronary syndromes. The aim of this study is to compare the bioresorbable Magmaris stent with the drug-eluting (drug-releasing) Xience stent in patients with acute coronary syndromes undergoing PCI.

Who can participate?
Patients with acute coronary syndromes

What does the study involve?
Participants are randomly allocated to undergo PCI with either a bioresorbable stent or a drug-eluting stent. Participants in both groups are followed for 12 months with heart scans at 12 months.

What are the possible benefits and risks of participating?
The study will provide information about the effects of the coronary intervention at 12 months. There is a small risk (mainly minimal bleeding) with respect to repeat invasive imaging at 12 months.

Where is the study run from?
University Hospital Kralovske Vinohrady (Czech Republic)

When is the study starting and how long is it expected to run for?
March 2017 to January 2021

Who is funding the study?
1. University Hospital Kralovske Vinohrady (Czech Republic)
2. Charles University in Prague (Czech Republic)

Who is the main contact?
Petr Tousek
petr.tousek@fnkv.cz

Contact information

Type(s)
Public

Contact name
Mr Petr Tousek

ORCID ID
https://orcid.org/0000-0002-2598-3635

Contact details
Srobarova 50
Praha 10
Czech Republic
10034
+420 (0)267162621
petr.tousek@fnkv.cz

Additional identifiers

Protocol serial number
EK-VP-29-0-2017

Study information

Scientific Title
Bioresorbable magnesium-based sirolimus-eluting stent versus permanent metallic everolimus-eluting stent in patients with acute coronary syndromes

Acronym
PRAGUE-22

Study objectives
The bioresorbable magnesium-based sirolimus-eluting stent has similar 12-months efficacy compared to the everolimus-eluting metallic stent in patients with acute coronary syndromes.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 28/06/2017, University Hospital Kralovske Vinohrady Ethics Committee (Srobarova 1150/50, 100 34 Prague, Czech Republic; +420 (0)267 16 2272; eticka.komise@fnkv.cz), ref: EK-VP-29-0-2017

Primary study design
Interventional

Study design
Two-centre investigator-initiated academic randomized study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute coronary syndromes

Interventions
Participants are randomised using the envelope method into two arms. Both groups undergo percutaneous coronary intervention (PCI): one arm undergoes bioresorbable stent implantation (Magmaris stent) and the other group second-generation drug-eluting stent (XIENCE) implantation. Participants in both groups are followed for 12 months with control angiography and optical coherence tomography (OCT) imaging at 12 months.

Intervention Type
Device

Phase
Phase IV

Primary outcome(s)
Late lumen loss assessed by quantitative coronary angiography (QCA) and optical coherance tomography (OCT) at 12 months follow-up

Key secondary outcome(s)
1. Device and procedural success (devices implanted by physician with optimal expansion, time) recorded at the time of the procedure
2. Clinical combined endpoints (death, stent thrombosis, target vessel myocardial infarction, clinically driven target lesion failure), measured at 12 months
3. Magmaris resorption assessed by OCT at 12 months
4. Healing state assessed by OCT at 12 months

Completion date
31/01/2021

Eligibility

Key inclusion criteria
Patients were included if they presented with:
1. ST-elevation myocardial infarction (STEMI) <24 hours since the onset of symptoms or
2. Non-ST-elevation myocardial infarction (non-STEMI) or

3. Unstable angina caused by thrombotic acute coronary stenosis and coronary artery with stenosis diameter suitable for implantation of both investigated types of stents (vessel diameter between 2.7 and 3.7 mm)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
50

Key exclusion criteria
1. Cardiogenic shock or pulmonary oedema
2. Expected survival less than 3 years due to severe comorbidities
3. Contraindication of 12 months dual antiplatelet treatment including an indication to treatment with peroral anticoagulants
4. Diffuse calcifications or extreme tortuosity of the target vessel
5. In-stent restenosis or stent thrombosis as the culprit lesion
6. Left main stenosis

Date of first enrolment
01/07/2017

Date of final enrolment
20/01/2020

Locations

Countries of recruitment
Czech Republic

Study participating centre
University Hospital Kralovske Vinohrady
Srobarova 50
Prague
Czech Republic
10034

Study participating centre

AGEL
Cardiology Department
Kyjevská 44
Pardubice
Czech Republic
53203

Sponsor information

Organisation
Fakultní nemocnice Královské Vinohrady

ROR
https://ror.org/04sg4ka71

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

Funder Name
University Hospital Kralovske Vinohrady, Intercardis project EU Nr. CZ.02.1.01/0.0/0.0/16_026/0008388

Results and Publications

Individual participant data (IPD) sharing plan

Participant level data will be available upon request to principal investigator Petr Tousek (petr.tousek@fnkv.cz). Data are already available, will be available for 5 years, and are anonymized. Participant consent was not obtained for sharing other data.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/09/2021	13/09/2021	Yes	No