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Collection of Information on the long-term results of treatment with the Supraflex™ Cruz drug-releasing blood vessel scaffold

Submission date
01/07/2020

Recruitment status
No longer recruiting

Registration date
01/07/2020

Overall study status
Completed

Last Edited
29/10/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Coronary heart disease (CHD), also known as ischemic heart disease, is one of the leading causes of death worldwide. CHD develops because of the build-up of fatty deposits (plaque) on the walls of the coronary arteries (the arteries that supply the heart with oxygen-rich blood). When arteries are blocked or narrowed, the heart does not receive enough blood to function properly, which can cause pain and tightness in the chest (angina), or a heart attack. An angioplasty is a common procedure where a thin tube (catheter) is placed inside the narrowed blood vessel. A small balloon on the tip of the catheter is gradually inflated to reopen the artery and flatten the blockage against the artery wall. In some cases, the surgeon also places a mesh-like tube (stent) into the artery to keep it open. One of the main problems following this type of surgery is that the artery may re-narrow and become blocked again (restenosis), as the cells which make up the obstruction multiply (proliferate). New techniques have been developed where the stent placed in the artery is coated in a drug which prevents cell proliferation (drug-eluting stent). The Supraflex™ Cruz Stent is a type of drug-eluting stent which uses the drug sirolimus to prevent restenosis. The aim of this study is to look at patients who have had a Supraflex™ Cruz Stent to find out if it is a safe and efficient way of preventing restenosis and future heart problems.

Who can participate?
Adults who have had a Supraflex™ Cruz Stent implanted as part of their clinical care.

What does the study involve?
Participants who are having a Supraflex™ Cruz Stent implanted are asked for their consent to take part in the study. The patients are asked to attend a follow-up appointment 12 months after their operation so that any blockages in their stent (stent thrombosis) can be measured, using an angiogram (a scan of the coronary arteries). The patients are also interviewed in order to find out whether there have been any problems since their operation.

What are the possible benefits and risks of participating?
There are no direct benefits or risks to patients taking part in this study

Where is the study run from?
Freeman Hospital (lead centre) and around 30 other hospitals in the UK

When is the study starting and how long is it expected to run for?
April 2018 to January 2023

Who is funding the study?
Sahajanand Medical Technologies Pvt. Ltd (India)

Who is the main contact?
Manoj Virupil, manoj@smt.in

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
246372

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 246372

Study information

Scientific Title
Prospective evaluation of thin-strut biodegradable polymer-coated Supraflex sirolimus-eluting stents in an all-comers patient population (S-FLEX UK-II)

Acronym
S-FLEX UK-II

Study objectives
To evaluate the clinical safety and performance of thin-strut biodegradable polymer-coated Supraflex Cruz sirolimus-eluting stents in an all-comers patient population requiring stent implantation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/08/2019, South West - Cornwall & Plymouth REC (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8214; cornwallandplymouth.rec@hra.nhs.uk), ref: 18/SW/0130

Study design
Multi-centre observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Atherothrombosis

Interventions
Once a patient has been identified as potentially meeting the inclusion and exclusion criteria written informed consent is obtained prior to the patient’s enrollment. Potential participants will have up to 24 hours to consider the information presented to them, after which signed consent will be sought. It should be noted that the patient would have already provided consent for the DES implantation procedure as per normal standard of care at the investigational site.

The total duration of observation is 12 months with a follow up at 12 months.
The total duration of the follow-up at 12 months is no longer than 1 hour.

Intervention Type
Other

Primary outcome measure
The safety and efficacy of the Supraflex Cruz stent measured through patient interviews and the review of medical notes at the 12 month follow up

Secondary outcome measures
Measured using a review of patient records:
1. Procedural endpoints [at the end of the index procedure (12 months)]
1.1. Device success, lesion success, procedural success
2. Safety and efficacy endpoints [30 days and 12 months]
2.1. Overall stent thrombosis
2.2. All deaths (cardiac, vascular and non-cardiovascular)
2.3. Any myocardial infarction (Q wave and non-Q wave MI)
2.4. Any repeat revascularization (target lesion and target vessel revascularization)
2.5. Target Lesion Failure (TLF)
2.6. Target Vessel Failure (TVF): a composite endpoint of cardiac death, target vessel myocardial infarction and clinically driven target vessel revascularization

Overall study start date
09/04/2018

Completion date
10/01/2023

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Symptomatic coronary disease
3. Clinical indication for PCI and stenting of at least one coronary lesion visually confirmed on coronary angiography
4. Only Supraflex Cruz stent(s) is/are to be implanted into the coronary vasculature during the index procedure
5. Give informed consent to participate in this registry and sign the informed consent form approved by the institutional review board of each registry site before the index PCI
6. Agree to undergo all clinical follow-up procedures specified in the study protocol (S-FLEX UK-II) for this registry

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

3,000

Total final enrolment
1904

Key exclusion criteria
1. Cardiogenic shock.
2. Pregnant or possibly pregnant
3. Known hypersensitivity or contraindication to aspirin, clopidogrel, ticlopidine, heparin or any other anticoagulation / antiplatelet therapy required for PCI, cobalt chromium, sirolimus or contrast media
4. Scheduled to undergo elective surgery within 12 months post-index PCI
5. Currently participating in a clinical study of another drug or medical device and in whom assessment of the primary endpoint of that study has not been completed or clinically interferes with the endpoints of this registry
6. Mental incapacity, unwillingness or language barrier precluding understanding of the registry procedure or cooperation with registry site personnel

Date of first enrolment
10/03/2020

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle Upon Tyne
United Kingdom
NE7 7DN

Study participating centre
University Hospital of Wales - Cardiff
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
Bedford Hostpital
King’s Place
Britannia Road
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United Kingdom
MK42 9DJ

Study participating centre
Wigan Hospital
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Wigan
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WN1 1XX

Sponsor information

Organisation
Sahajanand Medical Technologies Pvt. Ltd (SMT)

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Sponsor type
Industry

Website
www.SMTPL.com

Funder(s)

Funder type
Industry

Funder Name
Sahajanand Medical Technologies Pvt. Ltd (SMT)

Results and Publications

Publication and dissemination plan
Planned publication of results through peer reviewed scientific journals, conference presentations and publications on the SMT website.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Results article	safety and performance	22/10/2024	29/10/2024	Yes	No