

Collection of information on the long-term results of treatment with the Supraflex™ drug eluting stent (the S-FLEX UK Registry)

Submission date 21/10/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/11/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/01/2019	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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™ 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™ 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™ Stent implanted as part of their clinical care.

What does the study involve?

Participants who are having a Supraflex™ 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 10 other hospitals in the UK

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

July 2015 to January 2016

Who is funding the study?

Sahajanand Medical Technologies Pvt. Ltd (India)

Who is the main contact?

Mr Cheran Uthirapathi

Contact information

Type(s)

Scientific

Contact name

Mr Cheran Uthirapathi

Contact details

Sahajanand Medical Technologies Pvt. Ltd (SMT)
Sahajanand Estate
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Surat
India
395004

Additional identifiers

EudraCT/CTIS number

2015-004513-24

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

19301

Study information

Scientific Title

Prospective evaluation of the Supraflex™ sirolimus-eluting coronary stent system in a 'real-world' patient population: the S-FLEX UK Registry

Study objectives

The aim of this study is to evaluate the safety and efficacy of the Supraflex™ sirolimus-eluting coronary stent system in a 'real world' patient population requiring stent implantation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Wales - Regional Ethics Committee 7, 21/05/2015, ref: 15/WA/0121

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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Cardiovascular disease; Subtopic: Cardiovascular (all Subtopics); Disease: 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.

We will simply identify those who have had the Supraflex stent, so they can be followed up.

Intervention Type

Other

Primary outcome measure

The safety and efficacy of the Supraflex stent is measured through patient interviews and the review of medical notes at the 12 month follow up.

Secondary outcome measures

1. Overall stent thrombosis measured using an angiogram at 12 months
2. Overall mortality rate is determined by contacting the patients' GP at 12 months

3. Myocardial infarction rate is measured using a 12-lead ECG at 12 months
4. Target vessel failure measured using an angiogram at 12 months
5. Rate of major adverse cardiac events measured through patient interviews and review of medical notes at 12 months

Overall study start date

10/07/2015

Completion date

31/01/2016

Eligibility

Key inclusion criteria

1. Aged 18 years or over
2. The patient, or legal representative, consents to participate and has authorised the collection and release of his/her medical information
3. Treating physician has electively implanted at least one Supraflex™ Stent as part of the patient's planned clinical care
4. The patient is willing and able to cooperate with study procedures and required follow up visits

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 500; UK Sample Size: 500

Key exclusion criteria

1. Women with known pregnancy or who are lactating
2. High probability of non-adherence to the follow-up requirements (due to social, psychological or medical reasons)
3. Currently participating in another study that has not completed the primary endpoint or that clinically interferes with the current registry requirements
4. Planned surgery within 6-months of PCI unless dual anti-platelet therapy is maintained throughout the perioperative period

Date of first enrolment

10/07/2015

Date of final enrolment

31/01/2016

Locations

Countries of recruitment

England

Scotland

United Kingdom

Wales

Study participating centre

Freeman Hospital

Freeman Road
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre

Royal Blackburn Hospital

Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre

Blackpool Teaching Hospital

38 Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre

Scunthorpe General Hospital

Cliff Gardens
Scunthorpe
United Kingdom
DN15 7BH

Study participating centre
Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
Eastbourne District General Hospital
King's Drive
Eastbourne
United Kingdom
BN21 2UD

Study participating centre
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Milton Keynes University Hospital
H8 Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

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

Study participating centre

New Cross Hospital
Wednesfield Road
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Ninewells Hospital and Medical School
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
Sahajanand Medical Technologies Pvt. Ltd (SMT)

Sponsor details
Sahajanand Medical Technologies Pvt. Ltd (SMT)
Sahajanand Estate
Wakhariawadi-Near Dabholi Char Rasta Ved Road
Surat
India
395004

Sponsor type
Hospital/treatment centre

Website
www.SMTPL.com

ROR
<https://ror.org/01vm4bk04>

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

30/06/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No