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# 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

**Registration date**
24/11/2015

**Overall study status**
Completed

**Last Edited**
29/01/2019

**Condition category**
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
Wakhariawadi-Near Dabholi Char Rasta Ved Road
Surat
India
395004

# Additional identifiers

### Clinical Trials Information System (CTIS)
2015-004513-24

### Protocol serial number
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

### Study type(s)
Treatment

### 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(s)
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.

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### 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
United Kingdom

England

Scotland

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)

**ROR**
https://ror.org/01vm4bk04

# Funder(s)

**Funder type**
Industry

**Funder Name**
Sahajanand Medical Technologies Pvt. Ltd (SMT)

# Results and Publications

## 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |