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Systematic Assessment of the Cook Radial shEath Device

Submission date 05/10/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 17/10/2013	**Overall study status** Completed	
Last Edited 12/12/2017	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims

Coronary angiograms are performed to examine the condition of the arteries that supply blood to the heart muscle. Coronary angioplasty involves the widening of the heart arteries with a balloon, often followed by the placement of a metal mesh-like structure called a stent. Traditionally these have been performed by passing a narrow tube called a catheter through a sheath inserted into an artery in the groin called the femoral artery. There has been a rapidly growing trend to perform these procedures through an artery in the wrist called the radial artery. The radial route has the advantage of lower complications and patients are often able to move earlier following their procedures. The radial artery however is smaller than the femoral, it is also more muscular and prone to spasm. To help prevent this, radial sheaths can be coated with a slippery substance. In the past a small number of patients have reported a skin reaction at the puncture site (thought to be from this coating), a couple of weeks or so after their procedure. The manufacturers of the sheath have made changes to their product. The aim of this is to eliminate or reduce the chance of this reaction occurring. Subsequently the study team would now like to follow the patients after their procedure to confirm that their skin puncture heals satisfactorily. Other routine information about the performance of the sheath will also be collected such as whether the procedure could be completed as planned.

Who can participate?

Patients aged over 18 admitted to the study hospital for a planned radial coronary procedure

What does the study involve?

Participants undergo their procedure as normal. Before they go home, a member of the study team provides them with some additional and contact information. If they experience any problems with their puncture site, they are encouraged to contact the study team. If they do not experience a problem they are contacted at around 28 days to confirm the absence of problems.

What are the possible risks and benefits of participating?

There are no direct benefits to participants. Personal results are not used in any way without their permission. The overall anonymous group results of the study may be directly used to

inform the manufacturer of the optimal design of their product. There are no additional risks in taking part in the study. The risks are the same as those explained by the doctor when they were asked to consent for the procedure.

Where is the study run from?
Liverpool Heart and Chest Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2013 to April 2014

Who is funding the study?
Cook Medical (USA)

Who is the main contact for the study?
1. Mrs Christine Mars
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
801

Study information

Scientific Title
A prospective, single centre registry study recruiting consecutive patients to examine the safety, efficacy and subsequent incidence of cutaneous reaction with use of the Cook Flexor Radial Introducer Set

Acronym

SACRED

Study objectives
Observational study to describe the incidence of granuloma reactions observed after use of the study sheath device for radial access for coronary diagnostic and interventional procedures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service (NRES) Committee North West - Liverpool Central; 12/01/2010; ref: 09/H1005/72

Primary study design
Observational

Study design
Observational prospective single-centre registry study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Cutaneous granuloma formation following the use of radial introducer sheaths used in coronary angiography and angioplasty procedures

Interventions
Patients will be provided with some additional information prior to discharge. What they might expect with normal healing will be explained to them. Patients will be encouraged to contact the study team via email or dedicated phone line with voice messaging facilities. Such patients will be invited to return to the study centre for clinical review to allow formal assessment of the puncture site for the primary outcome measure. All other patients will be contacted by telephone, text or email at 28 days (+ 7 days) to confirm the absence of problems. Patients will equivocal responses will be invited for clinical assessment.

It is important to note that the sheath being studied is currently in use in all patients undergoing coronary angiography or angioplasty via the radial artery at the study centre. In participating in the study, patients are not being asked to trial a new or different sheath from any other patient.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
The incidence of granuloma formation by 28 days defined as an indurated, erythematous lesion, at least 3mm in its longest diameter, not related to haematoma

Key secondary outcome(s)

1. The rate of successful insertion of the study sheath device
2. The rate of successful completion of the coronary procedure through the initial sheath device
3. The incidence of administration of intra-arterial vasodilator agents for the management of coronary artery spasm (routine administration is not practice at the study centre)

The rate of other vascular complications
1. Small haematoma ≤ 3cm diameter
2. Large haematoma > 3cm diameter
3. The incidence of blood transfusion related to access site complications
4. The incidence of surgical or other interventional procedures for the management of vascular access complications
5. Delayed discharge necessitating an unplanned night or more in hospital related to vascular access complications

All secondary outcome measures are recorded following the index procedure and prior to hospital discharge.

Completion date
30/04/2014

Eligibility

Key inclusion criteria
1. Patients admitted for cardiac procedures with planned radial access
2. Patients under the care of a participating consultant

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients under 18 years of age
2. Patients unable to give informed consent
3. Patients who feel unable or unwilling to return to the study centre for outcome measure assessment
4. Patients who have had previous procedures through the same radial access site
5. Emergency or high risk procedures with survival doubt
6. Where there is a known sensitivity to the study device

Date of first enrolment
09/10/2013

Date of final enrolment

06/03/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Liverpool Heart and Chest Hospital NHS Foundation Trust
Liverpool
United Kingdom
L14 3PE

Sponsor information

Organisation
Liverpool Heart and Chest Hospital NHS Foundation Trust (UK)

ROR
https://ror.org/000849h34

Funder(s)

Funder type
Industry

Funder Name
Cook Medical

Alternative Name(s)
COOK MEDICAL LLC, Cook

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration