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Randomised Comparison Of Introducer Sheaths And Compression Devices In Patients Undergoing Transradial Coronary Procedures

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Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 12/08/2010	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr S Rathore

Contact details
Department of Cardiology
The Cardiothoracic Centre
Thomas Drive
Liverpool
United Kingdom
L14 3PE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0054186616

Study information

Scientific Title

Study objectives
Radial artery spasm is a common complication and several small studies have shown conflicting results with the use of different spasmolytic cocktails prior to transradial access.

Several different length sheaths are used by radial operators and there are no studies done so far to compare different sheaths and their effects on access site outcomes and impact on radial artery physiology. Some radial operators routinely use different spasmolytic cocktail prior to transradial procedures with no studies so far convincingly supporting this action.

Several different post procedure haemostatic techniques have been used ranging from tourniquets, compression devices and hydrophilic wound dressings. Various haemostatic compression devices specific to radial artery are marketed and Radistop [RADI Medical Systems B] and TR Band [Terumo] are widely used. There are no comparative studies done between these compression devices on outcomes and patient tolerance.
Recently there have been reports of sterile inflammatory abscesses with the usage of sheaths with hydrophilic coatings. These inflammatory reactions are reported in 2-3% of cases [39-41].

The ramifications of radial artery occlusion and injury are important not only in patients undergoing repeat interventional procedures, but also in patients in whom the radial artery may be used as a conduit for coronary artery bypass surgery or in patients needing arterio venous fistula for haemodialysis. Radial artery spasm is a common morbidity which can cause considerable discomfort to the patient and can prevent successful completion of procedure. To assess the impact of length and hydrophilic coating of the transradial introducer sheath on incidence of radial artery occlusion, radial artery spasm, local inflammatory reaction and other vascular complications.

To compare the impact of the TR band and Radistop compression haemostatic devices on the time taken to achieve haemostasis, radial artery occlusion rates, local vascular complications and patients tolerance of the device.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective randomised single blinded single centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Thoracic

Interventions
We will invite and screen all patients considered for coronary catheterisation and coronary intervention by the transradial approach.

Patients will be allocated in random fashion to different treatment strategies.
Method of randomisation: simple randomisation by opening an envelope just before procedure in catheterisation laboratory. Continuous variables will be described as mean +/- SD and compared using Students t test. Categorical variables will be expressed as frequencies and compared by chi-square statistics.
Multivariate analysis will be performed to identify the predictors of radial artery spasm and radial artery occlusion.

This will be a prospective, randomised, single blinded, single centre study. Patients will be randomised in factorial design as follows:

1:1:1:1 Randomisation to following sheaths:

- Long [23 cm] hydrophilic coated sheath
- Long [23 cm] uncoated sheath
- Short [13 cm] hydrophilic coated sheath
- Short [13 cm] uncoated sheath

1:1 Randomisation to following compression devices to achieve haemostasis at the end of procedure

- TR band vs Radistop compression device

Intervention Type
Device

Phase
Not Specified

Primary outcome measure
Primary end points: Incidence of clinical radial artery spasm.

Secondary outcome measures
1. Incidence of radial artery occlusion rates
2. Incidence of local vascular complications
3. Incidence of sterile inflammatory reaction
4. Incidence of spontaneous recanalisation of radial artery

5. Time to achieve haemostasis
6. Patient tolerance of haemostatic deviceThis study will help us in defining the problem of radial artery spasm, radial artery occlusion and local vascular complications.

This study results will help us in deciding the best sheath and compression device from the variety of products available commercially for transradial coronary procedures.

Overall study start date
01/09/2006

Completion date
01/09/2007

Eligibility

Key inclusion criteria
Sample size - Clinical radial artery spasm rates are reported between 20-30% [as per literature] and to detect 50% reduction in incidence of radial artery spasm, we need to recruit 175 [200] patients in each arm. This is with significance level of 0.05 [alpha error], and power of 80% [beta error- .02]. In total we need 800 patients with 200 patients in each arm of different sheath type. There will therefore be 400 patients in each arm of compression device randomisation [TR band vs. Radistop].

Target population - All patients considered for coronary angiography and coronary intervention by the transradial approach. Inclusion Criteria:
1. Intended transradial coronary procedure
2. Patient > 18 years of age and able to give informed consent.

All patients undergoing transradial procedure at the Cardiothoracic Centre, Liverpool under the care of JLM, RHS, RAP, NDP [after taking their permission] will be contacted about the study and procedures will be explained. Willing patients will then be assessed in detail and informed consent will be obtained.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
800

Key exclusion criteria

1. Unable or unwilling to give informed consent
2. Inability to demonstrate the presence of ulnar collateral circulation
3. Patients with A-V fistula or patients with chronic renal failure
4. Previous ipsilateral transradial procedure

Date of first enrolment
01/09/2006

Date of final enrolment
01/09/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Cardiology
Liverpool
United Kingdom
L14 3PE

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
The Cardiothoracic Centre Liverpool NHS Trust (UK) - NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	01/05/2010		Yes	No