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ANGIO-Seal™ or Manual Compression After Coronary Intervention Evaluation

Submission date
14/02/2006

Recruitment status
No longer recruiting

Registration date
14/02/2006

Overall study status
Completed

Last Edited
26/08/2009

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr J. Klijn

Contact details
Diagram B.V. Zwolle
Van Nahuysplein 6
Zwolle
Netherlands
8011 NB
+31 (0)38 4262997
j.klijn@diagram-zwolle.nl

Additional identifiers

Protocol serial number
NTR569; 9051

Study information

Scientific Title

Acronym

Angiocare

Study objectives
It is assumed that the incidence of the primary endpoint after manual compression will be 7% and after the Angio-Seal™ 2%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Single center prospective randomised open label active controlled parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Percutaneous Coronary Intervention (PCI)

Interventions
Manual compression or Angio-Seal™ closure device of arteria femoralis after PCI.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
Incidence of:
1. Severe hematoma at the puncture site or groin bleeding resulting in prolonged hospital stay or transfusion
2. Arteriovenous fistula formation at the puncture site and/or surgical intervention at the puncture site

Key secondary outcome(s))
The decrease of hemoglobin 1 day after inclusion.

Completion date
01/02/2009

Eligibility

Key inclusion criteria

1. Percutaneous Coronary Intervention via the femoral artery, with either B or C
2. At least the following medication
2.1. Aspirin
2.2. Unfractionated Heparin
2.3. Clopidogrel 600 mg pre-loading dose
2.4. Glycoprotein 2B/3A inhibitor
3. Percutaneous coronary intervention (PCI) within 4 hours after administration of thrombolysis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Age <18 years
2. Serious comorbidity such as cancer
3. Advanced cerebrovascular disease
4. Unwilling or unable to sign the consent form for participation
5. Females of childbearing age not using medically prescribed contraceptives
6. Unsuitable access site (severe PVD, poor location)

Date of first enrolment
19/01/2006

Date of final enrolment
01/02/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Diagram B.V. Zwolle
Zwolle
Netherlands
8011 NB

Sponsor information

Organisation
Diagram BV (Netherlands)

ROR
https://ror.org/03rhyyh86

Funder(s)

Funder type
Industry

Funder Name
St. Jude Medical Nederland BV (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration