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ANGIO-Seal™ or Manual Compression After Coronary Intervention Evaluation

Submission date 14/02/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 14/02/2006	**Overall study status** Completed	
Last Edited 26/08/2009	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
The decrease of hemoglobin 1 day after inclusion.

Overall study start date
19/01/2006

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

Age group
Adult

Sex
Both

Target number of participants
614

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)

Sponsor details
van Nahuysplein 6
Zwolle
Netherlands
8011 NB

Sponsor type
Industry

Website
http://www.diagram-zwolle.nl

ROR
https://ror.org/03rhyyh86

Funder(s)

Funder type
Industry

Funder Name
St. Jude Medical Nederland BV (Netherlands)

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