

# ANGIO-Seal or manual Compression After Coronary intervention Evaluation.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON28741

### Source

NTR

### Brief title

Angiocare

### Health condition

Patients undergoing PCI, who have a high risk of bleeding

## Sponsors and support

**Primary sponsor:** Diagram B.V.

van Nahuysplein 6

8011 NB Zwolle

**Source(s) of monetary or material Support:** St. Jude Medical

## Intervention

## Outcome measures

### Primary outcome

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**

The decrease of hemoglobin, 1 day after inclusion.

## **Study description**

### **Background summary**

It concerns a single center prospective randomized study to compare the Angio-Seal closure device with manual compression in a high-risk patient population. The randomization is 1:1 to receive or not to receive an Angio-Seal. All patients will be treated with aspirin, clopidogrel (with high loading dose ), a glycoprotein 2B/3A inhibitor and unfractionated heparin during the PCI. In addition, a non-randomized group consisting of patients with standard clopidogrel dosing will all be closed with Angio-Seal , and their data included in the analysis as an additional control group.

### **Study objective**

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

### **Intervention**

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

## **Contacts**

### **Public**

Diagram B.V. Zwolle  
Dokter Stolteweg 96

J. Klijn  
Dokter Stolteweg 96

Zwolle 8025 AZ  
The Netherlands

+31 (0)38 4262997

**Scientific**

Diagram B.V. Zwolle

Dokter Stolteweg 96

J. Klijn

Dokter Stolteweg 96

Zwolle 8025 AZ

The Netherlands

+31 (0)38 4262997

## Eligibility criteria

### Inclusion criteria

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

### 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).

## Study design

### Design

Study type:

Interventional

Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	19-01-2006
Enrollment:	614
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	19-01-2006
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
NTR-new	NL525
NTR-old	NTR569
Other	: 9051
ISRCTN	ISRCTN22655249

## Study results

### Summary results

1. Resnic F, Blake G, Ohno-Machado L, Selwyn A, Popma J, Rogers C. Vascular closure devices and the risk of vascular complications after percutaneous coronary intervention in patients receiving glycoprotein IIb/IIIa inhibitors. *Am J Cardiol*. 2001;88:493-496.
2. Omoigui N, Califf R, Pieper K, et al. Peripheral vascular complications in the Coronary Angioplasty Versus Excisional Arterectomy Trial (CAVEAT-I). *J Am Coll Cardiol*. 1995;26:922-930.
3. Oweida SW, Roubin, GS, Smith RB III, Salam AQA. Postcatheterization vascular complications associated with percutaneous transluminal coronary angioplasty. *J Vasc Surg* 1990;12:310-5.
4. McCann RI, Schwartz LB, Pieper KS. Vascular complications of cardiac catheterization. *J Vasc Surg* 1991;14:375-81.
5. Muller DW, Shamir KJ, Ellis SG, Topol EJ. Peripheral vascular complications after conventional and complex percutaneous coronary interventional procedures. *Am J Cardiol* 1992;69:63-8.
6. Juergens CP, Leung DY, Crozier JA, et al. Patient tolerance and resource utilization associated with an arterial closure versus an external compression device after percutaneous coronary intervention. *Catheter Cardiovasc Interv* 2004;63:166-70.
7. Koreny M, Riedmuller E, Nikfardjam M, Siostrzonek P, Mullner M. Arterial Puncture Closing Devices Compared With Standard Manual Compression After Cardiac Catheterization. *JAMA* 2004;291:350-7.
8. Vaitkus PT. A meta-analysis of percutaneous vascular closure devices after diagnostic catheterization and percutaneous coronary intervention. *J Invasive Cardiol* 2004;16:243-6.
9. Kastrati A, Mehilli J, Schuhlen H, et al. A clinical trial of abciximab in elective percutaneous coronary intervention after pretreatment with clopidogrel. *N Engl J Med* 2004;350:232-8.
10. Lenderink T, Boersma E, Ruzyllo W, et al. Bleeding events with abciximab in acute coronary syndromes without early revascularization: An analysis of GUSTO IV-ACS. *Am Heart J*. 2004;147:865-73.
11. Exaire JE, Dauerman HL, Topol EJ, et al. Triple antiplatelet therapy does not increase femoral access bleeding with vascular closure devices. *Am Heart J* 2004;147:31-4.
12. Boccalandro F, Assali A, Fujise K, Smalling RW, Sdringola S. Vascular access site complications with the use of closure devices in patients treated with platelet glycoprotein IIb/IIIa inhibitors during rescue angioplasty. *Cather Cardiovasc Interv* 2004;63:284-9.