A randomized trial of the effect of antiplatelet therapy (Aspirin, Aspirin and Clopidogrel or Ticagrelor) on the occurrence of atherothrombotic events following lower extremity peripheral transluminal angioplasty.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28759

Source
NTR

Brief title
ASCOT

Health condition

antiplatelet therapy, peripheral transluminal angioplasty

Sponsors and support

Primary sponsor: Antonius Hospital Nieuwegein, Medisch Centrum Alkmaar.
Source(s) of monetary or material Support: Self-financing

Intervention

Outcome measures

Primary outcome

Primary endpoint is the occurrence of the cardiovascular events myocardial infarction, in-stent thrombosis, re-intervention due to hemodynamic re-stenosis, the occurrence of cerebrovascular event (CVA or/and TIA), peripheral embolus and mortality after one year of follow-up.

Secondary outcome

Secondary endpoint is occurrence of major and minor bleeding. According the TIMI criteria.

Study description

Study objective

Our hypothesis is that both dual therapy with aspirin and clopidogrel or ticagrelor alone will lead to a lower occurrence of atherothrombotic events in patients following endovascular intervention compared to aspirin. We also hypothesize that the bleeding risk of ticagrelor will be non-inferior compared to clopidogrel and aspirin.

Study design

Patients will receive regular follow-up, at 12 months, including duplex ultrasound at 12 months. All data will be prospectively collected and entered into a central database. Clinical follow-up will be obtained by contacting all patients at 12 months, and a double check will be performed on the basis of source documents obtained from medical records. In case of death the general practitioner will be asked for the possible reason for death

Intervention

Intervention is comparing dualtherapy aspirin (80mg)/clopidogrel (75mg) to ticagrelor (90mg) and the current practice aspirin 80mg.

Contacts

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Eligibility criteria

Inclusion criteria

All patients presented for percutaneous endovascular intervention are eligable for inclusion. Inclusion criteria: (1) lesions to the iliac, femoropopliteal and below the knee (BTK) arteries; (2) eligibility of lesions for percutaneous transluminal angioplasty (PTA) or recanalization with or without additional stenting (ST), (3) all TASC lesions [16]; (4) all Rutherford (1-6) classes.

Exclusion criteria

Exclusion criteria are patients with reported intolerance or hypersensitivity for the study medications, the use of anticoagulant therapy (coumarin derivatives; acenocoumarol / fenprocoumon / warfarin), the use of non-steroidal anti-inflammatory drugs in the two weeks prior to the venapuncture to determine eventual aspirin resistance, a history of platelet/bleeding abnormalities and a platelet count < 100x*10^6/dl.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2016
Enrollment:	1252
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL5538
NTR-old	NTR5658
Other	: 56795

Study results