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.

Gepubliceerd: 04-11-2015 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28759

Bron
NTR

Verkorte titel
ASCOT

Aandoening

antiplatelet therapy, peripheral transluminal angioplasty

Ondersteuning

Primaire sponsor: Antonius Hospital Nieuwegein, Medisch Centrum Alkmaar.
Overige ondersteuning: Self-financing

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2016
Aantal proefpersonen:	1252
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5538
NTR-old	NTR5658
Ander register	: 56795

Resultaten