Dipyridamol opbouw in secundaire preventie van beroerte.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24084

Source
NTR

Brief title
DOSE

Health condition

neurology, dipyridamole, headache, stroke, neurologie, dipyridamol, hoofdpijn, beroerte, CVA, TIA

Sponsors and support

Primary sponsor: Albert Schweitzer Hospital
Source(s) of monetary or material Support: Albert Schweitzer Hospital

Intervention

Outcome measures

Primary outcome

Headache frequency.

Secondary outcome

N/A

Study description

Background summary

The ESPS2 (1996) and ESPRIT (2006) studies have proven that secondary preventive therapy with acetylsalicylic acid combined with dipyridamole is more effectiev preventive therapy after stroke than treatment with one of the components. Headache is a frequent side-effect of dipyridamole. Dose escalation helps to reduce this side-effect. National and international guidelines state that dipyridamole dose has to be escalated gradually, but non of the guidelines mentions a dose escalation scheme. In practice different hospitals use different schemes. There is no research that indicates the best dose escalation scheme.

Study objective

Treatment starting with a low dose dipyridamole reduces the side-effect headache with 25%.

Study design

Patients fill out a diary on day 1, 3, 5, 7, 14, 21 and 28 of the study period.

Intervention

Two study arms, 4 weeks medication.

Both arms: Two weeks acetylsalicylic acid 160 mg once daily and week 3 and 4 80 mgs once daily. Further:

1. Week 1 and 2, 200 mgs dipyridamole retard once daily. Week 3 and 4 dipyridamole retard 200 mgs twice daily;

2. Week 1, 75 mgs dipyridamole once daily. Week 2, 75 mgs dipyrdidamole twice daily. Week 3, 200 mgs retard once daily and week 4 200 mgs retard twice daily.

Contacts

Public
Albert Schweitzerziekenhuis
Postbus 444
N.C.M. Vos, de

Dordrecht 3300 AK
The Netherlands
+31 (0)78 6542538
Scientific
Albert Schweitzerziekenhuis
Postbus 444
N.C.M. Vos, de
Dordrecht 3300 AK
The Netherlands
+31 (0)78 6542538

Eligibility criteria

Inclusion criteria

1. Age > 18 years;

2. Ischemic CVA or TIA;

3. Patients starting treatment with acetylsalicylic acid combined with dipyridamole accoriding to Dutch standards;

4. Able to fill out a diary.

Exclusion criteria

Patients not starting treatment with acetylsalicylic acid and dipyrdamole according to Dutch standards.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2011
Enrollment:	114
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-06-2011
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	NL2809
NTR-old	NTR2950
Other	METC / CCMO : 2010-022913-25 / NL34184.101.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A