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European/Australasian Stroke Prevention in Reversible Ischaemia Trial

Submission date	Recruitment status	[_] Prospectively registered
23/06/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/05/2020	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00161070

Protocol serial number
N/A

Study information

Scientific Title
European/Australasian Stroke Prevention in Reversible Ischaemia Trial: ESPIRIT

Acronym
ESPRIT

Study objectives
Results of trials of aspirin and dipyridamole combined versus aspirin alone for the secondary prevention of vascular events after ischaemic stroke of presumed arterial origin are inconsistent. The aim of the study is to resolve this uncertainty.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ischaemia

Interventions
Secondary prevention after transient ischaemic attack or non-disabling ischaemic stroke.

Three treatment strategies:
1. Oral anticoagulation (international normalised ratio [INR] 2.0-3.0)
2. The combination of aspirin (acetylsalicylic acid [ASA]) (in any dose between 30 mg and 325 mg daily) and dipyridamole (400 mg daily)
3. ASA (in any dose between 30 mg and 325 mg daily)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Aspirin, dipyridamole

Primary outcome(s)
Composite of death from all vascular causes, non-fatal stroke, non-fatal myocardial infarction, or major bleeding complication, whichever happened first.

Key secondary outcome(s))

1. Death from all causes
2. Death from vascular causes
3. Death from vascular causes or nonfatal stroke
4. Fatal or nonfatal stroke
5. Death from vascular causes, nonfatal stroke, nonfatal myocardial infarction or vascular intervention
6. Major bleeding complications
7. Amputations of lower extremities
8. Retinal infarction or bleeding

Completion date
01/12/2006

Eligibility

Key inclusion criteria
1. Patients presenting in the participating hospitals with a transient ischaemic attack (TIA) or non-disabling stroke of atherosclerotic origin
2. Randomisation within 6 months after the TIA or minor stroke
3. Modified Rankin scale of 3 or less

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. (Contra)indication to, or intolerance to, anticoagulants, dipyridamole, or aspirin
2. Disease expected to cause death within weeks or months
3. Source of embolism in the heart
4. Moderate or severe ischemic damage to the white matter of the brain (leukoaraiosis)
5. Anemia, polycythemia, thrombocytosis, or thrombocytopenia
6. Planned carotid endarterectomy
7. Intracranial bleeding or cerebral tumour
8. TIA or stroke caused by vasculitis, migraine, or dissection
9. Severe hypertension
10. Liver failure
11. Pregnancy
12. Chronic alcohol abuse

Date of first enrolment
01/07/1997

Date of final enrolment
01/12/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Utrecht
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
University Medical Center Utrecht (Netherlands)

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Other

Funder Name
Netherlands Heart Foundation (Netherlands)

Funder Name
UK Stroke Association (UK)

Funder Name
University Medical Center Utrecht (Netherlands)

Funder Name
Janivo Foundation (Netherlands)

Funder Name
French Ministry of Health (France)

Funder Name
Netherlands Thrombosis Foundation (Netherlands)

Funder Name
European Commission (ref: QLK6-CT-2002-02332)

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/05/2006		Yes	No
Results article	results	29/05/2012		Yes	No