

European/Australasian Stroke Prevention in Reversible Ischaemia Trial

Submission date 23/06/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 08/05/2020	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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

Study information

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

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