

Preventive Antibiotics in Stroke Study

Submission date 17/03/2010	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 06/04/2010	Overall study status Completed	☒ Statistical analysis plan ☒ Results
Last Edited 29/03/2023	Condition category Circulatory System	☐ 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

Study information

Scientific Title
Preventive ceftriaxone to improve functional health in patients with stroke by preventing infection: a multicentre prospective randomised controlled trial

Acronym
PASS

Study objectives
We hypothesise that preventive use of the antibiotic ceftriaxone improves functional health outcome in patients with stroke by preventing infection.

Ethics approval required

Old ethics approval format

Ethics approval(s)

METC of the Academic Medical Center in Amsterdam pending approval as of 17/03/2010

Primary study design

Interventional

Study design

Multicentre prospective randomised open-label blinded endpoint trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Stroke, infection

Interventions

Our intervention group will be treated with optimal medical care and ceftriaxone 2000 mg, intravenously, 1 time daily, for 4 days. The control group will receive the optimal medical care without ceftriaxone. The total duration of follow-up is 3 months; the primary outcome will then be assessed in a structured interview by telephone.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Ceftriaxone

Primary outcome(s)

Functional health at 3-month follow-up, as assessed by the modified Rankin scale (mRS) dichotomised as a favorable outcome (mRS 0 - 2) or an unfavorable outcome (mRS 3 - 6)

Key secondary outcome(s)

1. Death rate at discharge and 3 months
2. Infection rate during hospital admission
3. Length of hospital admission
4. Volume of post-stroke care
5. Use of antibiotics during the 3 months follow-up
6. Functional health using the full ordinal scoring range of the mRS
7. Quality adjusted life years (QALYs)
8. Costs

Completion date

01/05/2014

Eligibility

Key inclusion criteria

1. Aged greater than or equal to 18 years, either sex
2. Stroke (ischaemic and haemorrhagic)
3. Any measurable neurological deficit defined as National Institutes of Health Stroke Scale (NIHSS) greater than 1
4. Stroke onset less than 24 hours
5. Admission

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

2470

Key exclusion criteria

1. Symptoms or signs of infection on admission requiring antibiotic therapy
2. Use of antibiotics less than 24 hours before admission
3. Pregnancy
4. Hypersensitivity for cephalosporin
5. Previous anaphylaxis for penicillin or penicillin-derivates
6. Subarachnoid haemorrhage

Date of first enrolment

01/05/2010

Date of final enrolment

01/05/2014

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Centre
Amsterdam
Netherlands
1100 DE

Sponsor information

Organisation

Academic Medical Centre (AMC) (Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Research organisation

Funder Name

Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands) (ref: 171002302)

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Funder Name

Netherlands Heart Foundation (Nederlandse Hartstichting) (Netherlands) (ref: CD 300006)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/04/2014		Yes	No
Results article	results	18/04/2015		Yes	No
Results article	results	01/07/2018	27/08/2019	Yes	No
Results article	results	01/01/2020	15/04/2020	Yes	No
Results article	sub study results	12/01/2021	15/01/2021	Yes	No
Abstract results	Substudy results abstract European Stroke Organisation Conference 2021	03/09/2021	29/03/2023	No	No
Other publications	Association between leukocyte counts and carotid artery stenosis	08/12/2022	28/12/2022	Yes	No
Statistical Analysis Plan	statistical analysis plan	01/10/2014		No	No