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Preventive Antibiotics in Stroke Study

Submission date 17/03/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 06/04/2010	**Overall study status** Completed	[X] Statistical analysis plan [X] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Multicentre prospective randomised open-label blinded endpoint trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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)

Secondary outcome measures
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

Overall study start date
01/05/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
3200

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)

Sponsor details
Department of Neurology
Meibergdreef 9
Amsterdam
Netherlands
1105AZ

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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
Statistical	statistical analysis plan	01/10			

Analysis Plan		/2014		No	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
Other publications	Association between leukocyte counts and carotid artery stenosis	08/12 /2022	28/12 /2022	Yes	No
Abstract results	Substudy results abstract European Stroke Organisation Conference 2021	03/09 /2021	29/03 /2023	No	No