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Preventive antibacterial short-term therapy in patients with acute ischemic infarction in the territory of the middle cerebral artery (MCA)

Submission date 08/06/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/07/2004	**Overall study status** Completed	
Last Edited 19/05/2008	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.charite.de/ch/neuro/forschung/teams/experimentell/pantheris.htm

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

Acronym
PANTHERIS

Study objectives
Strokes are frequently accompanied by severe bacterial infections (21 - 65% among unselected patients), 10 - 22% of which were pneumonias. Complicating infections constitute a leading cause of stroke mortality. We have been able to demonstrate in an animal model that a profound stroke related immunodepression contributes to the rise of complicating infections, and that these infections can effectively be avoided by preventive antibacterial therapy (PAT) with Moxifloxacin. Importantly, in this stroke model PAT not only prevents infections, it also improves survival and outcome, significantly.

The following primary hypothesis shall be tested:
1. PAT with Moxifloxacin reduces the incidence of complicating infections after (primary aim)

Secondary aims:
2. PAT also reduces the infarct volume and improves the neurological outcome
3. Stroke causes a immunodepression, which is mediated by the sympathetic nerve system
4. PAT does not lead to a development of resistency among facultatively pathogenous bacteriae

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the ethics committee of Charité Hospital on the 23rd September 2002.

Study design
Double blind, randomised and controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

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

Interventions
Patients of group A are being treated according to the current standards of therapy. With respect to antibiotics, they are fully and effectively treated as soon as an antibiotic medication is indicated i.e. as soon as an infection is diagnosed. For reasons of the double blind study design, during the first five days after stroke, these patients receive a placebo (Riboflavin) instead of a preventive antibacterial medication.

Patients of group B are being treated according to the new regimen under investigation with a preventive antibacterial medication (Moxifloxacin 400 mg intravenous [iv]) for five days. Patients with outbreak of an intercurrent infection, were treated according to standardised protocol (SOP). The study medication will be continued.

This design enables us to work with a placebo control and yet have all patients with infections properly treated according to the current medical standards. Thus, the use of a placebo control in this study does not imply that some patients receive an ineffective medication for a diagnosed condition. It means that the new therapeutic regimen of preventive treatment is being tested against the current standard of post hoc treatment.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Moxifloxacin

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2003

Completion date
30/06/2008

Eligibility

Key inclusion criteria
The double blind, randomised and controlled study will be carried out on two groups of about 40 patients each. Since patients with large infarctions in the territory of the middle cerebral artery and a subsequent severe neurological deficit (National Institutes of Health-Stroke-Scale [NIHSS]

greater than 11) have the highest risk of pneumonia, we include only this subpopulation of stroke patients in our study.

Inclusion criteria:
1. Severe ischemic strokes in MCA territory (area greater than 50% in cerebral computed tomography [CCT], NIHSS greater than 11)
2. Within 36 hours after stroke onset
3. Older than 18 years
4. No infection
5. No intracerebral bleeding

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Immunosupressive therapy
2. Pregnancy
3. Antibacterial therapy within the last 24 hours before inclusion
4. Contraindication for moxifloxacin

Date of first enrolment
01/06/2003

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
Germany

Study participating centre
Klinik für Neurologie
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10117

Sponsor information

Organisation
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

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Sponsor type
University/education

Website
http://www.charite.de/

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
University/education

Funder Name
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	14/05/2008		Yes	No