

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

<b>Submission date</b> 08/06/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/07/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/05/2008	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## 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

### Contact name

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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 an 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. Immunosuppressive 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

Berlin

Germany

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# Sponsor information

## Organisation

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

## Sponsor details

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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?
<a href="#">Results article</a>	Results	14/05/2008		Yes	No