

# Prevention of cerebrovascular and cardiovascular Events of ischaemic origin with teRutroban in patients with a history of ischaemic strOke or tRansient ischaeMic attack

<b>Submission date</b> 22/03/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/06/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/01/2018	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration and not expected to be available in the future

## Contact information

### Type(s)

Scientific

### Contact name

Prof Marie-Germaine Bousser

### Contact details

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France  
75010

## Additional identifiers

### EudraCT/CTIS number

2005-003700-10

### IRAS number

### ClinicalTrials.gov number

## Secondary identifying numbers

CL3-18886-012

# Study information

## Scientific Title

Prevention of cerebrovascular and cardiovascular Events of ischaemic origin with teRutroban in patients with a history oF ischaemic strOke or tRansient ischaeMic attack

## Acronym

PERFORM

## Study objectives

To demonstrate the superiority of terutroban over a marketed drug (antithrombotic agent) in reducing the number of cerebrovascular and cardiovascular events in patients with cerebrovascular diseases

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

First Ethics Committee approval in Italia on 06/12/2005, reference number: 42

## Study design

Randomized double-blind parallel-group study

## Primary study design

Interventional

## Secondary study design

Randomised parallel trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## 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

Ischaemic stroke

## Interventions

S 18886 (terutroban) versus antithrombotic agent

## Intervention Type

Drug

**Phase**

Not Applicable

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

Terutroban

**Primary outcome measure**

Cerebrovascular and cardiovascular events

**Secondary outcome measures**

Safety criteria

**Overall study start date**

22/02/2006

**Completion date**

31/03/2010

## Eligibility

**Key inclusion criteria**

Male or female aged at least 55 years with recent history of stroke or transient ischaemic attack

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

18000

**Key exclusion criteria**

Haemorrhagic stroke

**Date of first enrolment**

22/02/2006

**Date of final enrolment**

31/03/2010

## Locations

**Countries of recruitment**

Austria

Belgium  
Bulgaria  
Canada  
Chile  
China  
Croatia  
Czech Republic  
Finland  
France  
Greece  
Hong Kong  
India  
Ireland  
Korea, South  
Lithuania  
Mexico  
Morocco  
Netherlands  
New Zealand  
Norway  
Portugal  
Romania  
Singapore  
Slovenia  
Sweden  
Taiwan

Tunisia

Ukraine

**Study participating centre**

Hopital Lariboisiere

Paris

France

75010

## Sponsor information

**Organisation**

Institut de Recherches Internationales Servier (France)

**Sponsor details**

50 rue Carnot

Suresnes

France

92284

**Sponsor type**

Industry

**Website**

<http://www.servier.com/>

**ROR**

<https://ror.org/034e7c066>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Institut de Recherches Internationales Servier (France)

## Results and Publications

## Publication and dissemination plan

Publication plan:

All phases - Interventional studies ending before 01/10/2018: Summary results will be published on <https://clinicaltrials.servier.com/> within 12 months after the end of the study.

All phases - Interventional studies ending after 01/10/2018: Summary results and a lay summary will be published on <https://clinicaltrials.servier.com/> within 12 months after the end of the study.

Phase 3 only - The results will be published in scientific literature within 18 months after the end of the study.

## Intention to publish date

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from <https://clinicaltrials.servier.com/> if a Marketing Authorisation has been granted after 2014.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>				No	No
<a href="#">Results article</a>	results	11/06/2011		Yes	No
<a href="#">Results article</a>	results	01/08/2014		Yes	No
<a href="#">Results article</a>	results	01/04/2016		Yes	No
<a href="#">Results article</a>	results	01/04/2017		Yes	No