

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

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

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

2005-003700-10

Protocol serial number

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

Study type(s)

Treatment

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(s)

Cerebrovascular and cardiovascular events

Key secondary outcome(s)

Safety criteria

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Institut de Recherches Internationales Servier (France)

Results and Publications

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?
Results article	results	11/06/2011		Yes	No
Results article	results	01/08/2014		Yes	No
Results article	results	01/04/2016		Yes	No
Results article	results	01/04/2017		Yes	No
Basic results				No	No