ISRCTN66157730 https://doi.org/10.1186/ISRCTN66157730

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/06/2006	**Overall study status** Completed	
Last Edited 25/01/2018	**Condition category** Circulatory System	

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
Hopital Lariboisiere
Service de Neurologie
2 Rue Ambroise Pare
Paris
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?
Basic results				No	No
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