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

Registration date
13/06/2006

Overall study status
Completed

Last Edited
25/01/2018

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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

Primary study design
Interventional

Study design
Randomized double-blind parallel-group study

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