

S 05985 combination versus angiotensin II receptor blocker/calcium channel blocker: a comparison of blood pressure lowering - efficacy and safety

Submission date 02/09/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/04/2018	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

Prof G. Mancia

Contact details

Ospedale S. Gerardo
1 Divisione di Medicina
Via Donizetti, 106
Monza
Italy
20052

Additional identifiers

Clinical Trials Information System (CTIS)

2010-020945-28

Protocol serial number

CL3-05985-018

Study information

Scientific Title

Perindopril arginine/amlodipine versus valsartan/amlodipine antihypertensive strategies: efficacy and safety in mild to moderate hypertensive patients - a randomised, double-blind 6-month study followed by 8-month open label long-term follow-up with perindopril arginine /amlodipine

Study objectives

To evaluate the efficacy on blood pressure lowering and the safety of increasing doses of the S 05985 combination and to compare these effects with those of another commonly used antihypertensive drug combination at different doses.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval was obtained before recruitment of the first participants

Study design

International multicentre phase III randomised double blind open controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Essential arterial hypertension

Interventions

One oral or two capsules per day of:

1. S 05985 combination over a maximum duration of 14 months or
2. Angiotensin II receptor blocker/calcium channel blocker over a maximum duration of 6 months

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Perindopril arginine, amlodipine, valsartan

Primary outcome(s)

1. Efficacy of S 05985 combination versus comparator in blood pressure lowering
2. Safety assessment of treatments

Key secondary outcome(s)

1. Efficacy of both combination strategies on ABPM parameters
2. Long-term safety assessment of S 05985 combination (14 months)

Completion date

01/09/2012

Eligibility

Key inclusion criteria

1. Outpatients
2. Men or women
3. Aged 18 years old at least
4. Mild to moderate hypertensive patient

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Pregnancy or breastfeeding women
2. Secondary hypertension
3. Any patient suffering from an acute or chronic illness
4. Contraindication to any study treatments

Date of first enrolment

06/11/2010

Date of final enrolment

01/09/2012

Locations

Countries of recruitment

United Kingdom

Belgium

Brazil

Canada

Czech Republic

France

Germany

Italy

Korea, South

Latvia

Lithuania

Mexico

Netherlands

Portugal

Russian Federation

Singapore

Spain

Taiwan

Türkiye

Study participating centre

Ospedale S. Gerardo

Monza

Italy

20052

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

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2015		Yes	No
Basic results				No	No