

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

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

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### Contact details

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## 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?
<a href="#">Results article</a>	results	01/02/2015		Yes	No
<a href="#">Basic results</a>				No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes