







# 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	 Prospectively registered
		 Protocol not yet added
<b>Registration date</b> 25/10/2010	<b>Overall study status</b> Completed	 SAP not yet added
		 Results added
<b>Last Edited</b> 18/04/2018	<b>Condition category</b> Circulatory System	 Raw data not yet added
		 Study completed

## Plain English Summary

Not provided at time of registration and not expected to be available in the future

## Contact information

### Type(s)

Scientific

### Contact name

Prof G. Mancina

### Contact details

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

## Additional identifiers

### EudraCT/CTIS number

2010-020945-28

### IRAS number

### ClinicalTrials.gov number

**Protocol/serial number**

CL3-05985-018

## Study information

**Scientific Title**

Perindopril arginine/amlo地平ine versus valsartan/amlo地平ine 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 /amlo地平ine

**Study hypothesis**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Condition**

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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

06/11/2010

**Overall study end date**

01/09/2012

**Eligibility**

**Participant 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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

1600

**Participant 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

**Recruitment start date**

06/11/2010

**Recruitment end date**

01/09/2012

**Locations****Countries of recruitment**

Belgium

Brazil

Canada

Czech Republic

France

Germany

Italy

Korea, South

Latvia

Lithuania

Mexico

Netherlands

Portugal

Russian Federation

Singapore

Spain

Taiwan

Turkey

United Kingdom

**Study participating centre**

**Ospedale S. Gerardo**

Monza

Italy

20052

## 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

Current version as of 28/03/2018:

Summary results are published in <https://clinicaltrials.servier.com>.

For interventional Phase III studies ending after the 1st January 2014, the results are/will be published in scientific literature.

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 1st January 2014.

Previous version as of 24/01/2018:

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

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>				No	No
<a href="#">Results article</a>	results	01/02/2015		Yes	No