

Efficacy and safety of the S 05985 combination compared with each individual component: randomised, double-blind, placebo-controlled study over eight weeks in hypertensive patients

Submission date 11/07/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/01/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 20/04/2020	Condition category Circulatory System	☐ 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 Stéphane Laurent

Contact details

Hôpital Européen Georges Pompidou
20-40 rue Leblanc
Paris
France
75908

Additional identifiers

Clinical Trials Information System (CTIS)

2006-005797-44

Protocol serial number

CL2-05985-005

Study information

Scientific Title

Efficacy and safety of the S 05985 combination compared with each individual component: randomised, double-blind, placebo-controlled study over eight weeks in hypertensive patients

Study objectives

Efficacy and safety assessment of the S 05985 combination compared with each individual component and placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

CPP Ile de France XI, Saint Germain en Laye (France), 15/02/2007, ref : 07005

Primary study design

Interventional

Study design

International multicentre phase II randomised double-blind placebo-controlled study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Essential arterial hypertension

Interventions

S 05985 versus each component given separately during 8 weeks.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

S 05985

Primary outcome(s)

Change in blood pressure measured before and after 2, 4 and 8 weeks

Key secondary outcome(s)

1. Response to the treatment and normalisation of blood pressure
 2. Safety
- Measured before and after 2, 4 and 8 weeks

Completion date

15/07/2008

Eligibility

Key inclusion criteria

1. Men or women
2. 18 to 80 years
3. Essential uncomplicated mild to moderate hypertensive patients

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

1581

Key exclusion criteria

1. Very high cardiovascular risk patients
2. Severe disease
3. Pregnancy
4. Obesity
5. Secondary hypertension

Date of first enrolment

15/05/2007

Date of final enrolment

15/07/2008

Locations**Countries of recruitment**

France

Hungary

Latvia

Lithuania

Russian Federation

Ukraine

Study participating centre
Hôpital Européen Georges Pompidou
Paris
France
75908

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 1st January 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
Basic results			20/04/2020	No	No