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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

Registration date
23/01/2008

Last Edited
20/04/2020

Recruitment status
No longer recruiting

Overall study status
Completed

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

Contact name
Prof Stéphane Laurent

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

Additional identifiers

EudraCT/CTIS number
2006-005797-44

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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

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

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

Overall study start date
15/05/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1500

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)

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
Publication plan:
Summary results are published in https://clinicaltrials.servier.com.

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 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