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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	[X] Prospectively registered [_] Protocol
Registration date 25/10/2010	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 18/04/2018	**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

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Additional identifiers

EudraCT/CTIS number
2010-020945-28

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

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 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

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1600

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
Belgium

Brazil

Canada

Czech Republic

France

Germany

Italy

Korea, South

Latvia

Lithuania

Mexico

Netherlands

Portugal

Russian Federation

Singapore

Spain

Taiwan

Türkiye

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?
Basic results				No	No
Results article	results	01/02/2015		Yes	No