ISRCTN61335805 https://doi.org/10.1186/ISRCTN61335805

S 05985 combination versus AT1-Receptor Blocker/thiazide: a comparison of blood pressure lowering - efficacy and safety

Submission date	Recruitment status	[ ] Prospectively registered
24/01/2008	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
29/02/2008	Completed	[X] Results
Last Edited	Condition category	[ ] Individual participant data
18/04/2018	Circulatory System	

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
2006-005799-42

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CL3-05985-006

Study information

Scientific Title
Perindopril Amlodipine Regimen versus AT1-Receptor Blocker/thiazide: a comparison of Blood pressure Lowering: Efficacy and Safety. A randomised, double blind, 9 month study of the efficacy and safety of four uptitrated doses of oral fixed combinations of perindopril /amlodipine, including a comparison with uptitrated doses of oral fixed combination of irbesartan and hydrochlorthiazide in mild to moderate hypertension.

Study objectives
To assess the efficacy of 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.

Please note that as of 19/11/2012, Ireland and the Netherlands were added to the countries of recruitment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from an English Ethics Committee on 30/09/2007

Study design
International multicentre phase III randomised double-blind controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
S 05985 combination versus AT1-Receptor Blocker/ thiazide for 9 months

Intervention Type

Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
S 05985, thiazide

Primary outcome measure
1. Overall proportion of participants with controlled blood pressure (at 6 months)
2. Safety assessment

Secondary outcome measures
1. Efficacy versus comparator (at 6 months)
2. New onset of clinical events or condition of special interest

Overall study start date
05/12/2007

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Men or women
2. Over 18 years
3. Essential arterial hypertension

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
3000

Key exclusion criteria
1. Pregnancy, breast-feeding, childbearing potential without medically accepted method of contraception
2. Acute or chronic illness

3. Secondary hypertension
4. Malignant hypertension
5. Clinical symptomatic hypotension

Date of first enrolment
05/12/2007

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
England

Ireland

Netherlands

United Kingdom

Study participating centre
International Centre for Circulation Health
London
United Kingdom
W2 1PG

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 www.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 www.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 www.clinicaltrials.servier.com if a Marketing Authorisation has been granted after 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
Poster results	results in poster	01/06/2015		No	No