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

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

Contact name
Prof Neil Poulter

Contact details
International Centre for Circulation Health
Imperial College London
59 North Wharf Road
London
United Kingdom
W2 1PG

Additional identifiers

Clinical Trials Information System (CTIS)
2006-005799-42

Protocol serial number
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

Primary study design
Interventional

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

Study type(s)
Treatment

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

Ireland

Netherlands

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

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 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