The EUROPA study: EUropean trial on Reduction Of cardiac events with Perindopril in stable coronary Artery

Submission date	Recruitment status	Prospectively registered
14/10/2009	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
15/10/2009	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

Contact name

Prof K Fox

Contact details

Royal Brompton National Heart & Lung Hospital Sydney Street London United Kingdom SW3 6NP +44 (0)20 7351 8626 K.Fox@rbht.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CL3-09490-144

Study information

Scientific Title

Effects of perindopril on mortality/morbidity in patients with stable coronary artery disease without clinical heart failure: a double-blind, multicentre, randomised trial

Acronym

EUROPA

Study objectives

To evaluate the effect of perindopril on cardiovascular events in patients with stable coronary artery disease and without heart failure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval was obtained before recruitment of the first participants

Study design

Randomised double-blind placebo-controlled trial

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

Coronary artery disease

Interventions

Perindopril 8 mg per day (4 mg for patients aged 70 or older) or placebo for approximately 4 years treatment, follow-up at 3 months, 6 months and every 6 months thereafter.

Intervention Type

Drug

Phase

Drug/device/biological/vaccine name(s)

Perindopril

Primary outcome measure

Composite endpoint of cardiovascular mortality, non-fatal myocardial infarction and cardiac arrest resuscitation, measured at 3 months, 6 months and every 6 months thereafter

Secondary outcome measures

Composite endpoints of mortality, non-fatal acute myocardial infarction, unstable angina and cardiac arrest resuscitation and individual endpoints, measured at 3 months, 6 months and every 6 months thereafter

Overall study start date

22/10/1997

Completion date

20/05/2003

Eligibility

Key inclusion criteria

- 1. Aged 18 years or more, both genders
- 2. Stable documented coronary artery disease
- 3. Not scheduled for revascularisation

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

12230

Key exclusion criteria

- 1. Clinical signs of heart failure requiring treatment with an angiotensin converting enzyme (ACE) inhibitor
- 2. Uncontrolled treated hypertension
- 3. Clinically significant obstructive valvular disease
- 4. Hypertrophic cardiomyopathy

Date of first enrolment

22/10/1997

Date of final enrolment 20/05/2003

Countries of recruitment

Locations

Austria

Belgium			
Czech Republic			
Denmark			
England			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Ireland			
Italy			
Latvia			
Lithuania			
Netherlands			
Norway			
Poland			
Portugal			
Slovakia			
Spain			
Sweden			

Switzerland

Türkiye

United Kingdom

Study participating centre
Royal Brompton National Heart & Lung Hospital
London
United Kingdom
SW3 6NP

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

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results	. CC:			No	No
Results article	efficacy results	06/09/2003		Yes	No
Results article	risk reduction results	01/03/2015		Yes	No