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

Submission date 14/10/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/10/2009	**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

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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

Phase III

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

Locations

Countries of recruitment
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
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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				No	No
Results article	efficacy results	06/09/2003		Yes	No
Results article	risk reduction results	01/03/2015		Yes	No