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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

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

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Austria

Belgium

Czech Republic

Denmark

Estonia

Finland

France

Germany

Greece

Hungary

Ireland

Italy

Latvia

Lithuania

Netherlands

Norway

Poland

Portugal

Slovakia

Spain

Sweden

Switzerland

Türkiye

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

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 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?
Results article	efficacy results	06/09/2003		Yes	No
Results article	risk reduction results	01/03/2015		Yes	No
Basic results				No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes