ISRCTN31129526 https://doi.org/10.1186/ISRCTN31129526

Effect of Angiotensin Converting Enzyme Inhibition (ACEI) on C-Reactive Protein (CRP) Levels: The Ramipril CRP Randomized Evaluation (4R Trial)

Submission date
26/12/2005

Recruitment status
No longer recruiting

Registration date
06/01/2006

Overall study status
Completed

Last Edited
20/07/2009

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Subodh Verma

Contact details
Div of Cardiac Surgery
St. Michael's Hospital
University of Toronto
30 Bond Street
Toronto
Canada
M5B 1W8

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
4R Trial

Study objectives
ACE inhibition, with Ramipril 10 mg per day, will lower C-reactive protein levels in healthy middle-aged volunteers with elevated C-reactive protein levels

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yes, approved by Institutional Review Board University of Calgary, Faculty of Medicine February 2003 (2003020012Ram)

Study design
Randomized double blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Healthy volunteers with elevated levels of C-Reactive protein

Interventions
Ramipril 10 mg per day versus placebo for 12 weeks

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ramipril

Primary outcome measure
Change in CRP levels in Ramipril versus placebo arms

Secondary outcome measures
Change in endothelial function assessed by pulse wave tomography (photoacoustic tomography [PAT])

Overall study start date
01/03/2003

Completion date
30/10/2004

Eligibility

Key inclusion criteria
35-80 years of age, male or female, free of cardiovascular disease, and baseline CRP greater than 2 mg/l

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Structural heart disease or vascular disease
2. Systolic blood pressure greater than 160 or less than 100 mmHg
3. Renal or hepatic dysfunction
4. White blood cell (WBC) count greater than 12,000
5. Chronic inflammatory disease
6. Human Immunodeficiency Virus (HIV)
7. Known sensitivity to ACEI
8. Steroid use
9. Chronic (more than 2 weeks) use of non-steroidal anti-inflammatory drugs (NSAIDs)
10. Treatment with:
a. ACEI or Angiotensin II Receptor Blockers (ARB)
b. Lipid lowering agents
c. Hormone replacement therapy
d. Oral hypoglycemic agents
e. Aspirin

f. Antioxidants
11. Failure to give informed consent

Date of first enrolment
01/03/2003

Date of final enrolment
30/10/2004

Locations

Countries of recruitment
Canada

Study participating centre
Div of Cardiac Surgery
Toronto
Canada
M5B 1W8

Sponsor information

Organisation
Sanofi-Aventis (Canada)

Sponsor details
2150 St. Elzear Blvd
Laval
Canada
H7L 4A8

Sponsor type
Industry

Website
http://www.sanofi-aventis.ca

ROR
https://ror.org/01aptcd74

Funder(s)

Funder type

Industry

Funder Name
Sanofi-Aventis (Canada)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2009		Yes	No