

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	<input type="checkbox"/> Prospectively registered
Registration date 06/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/07/2009	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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