

Effect of a Polypill on middle-aged and elderly Iranians

Submission date 14/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/10/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/10/2011	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Tom Marshall

Contact details
Department of Public Health and Epidemiology
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT
+44 (0)121 414 7832
T.P.Marshall@bham.ac.uk

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Acronym

Poly-Iran

Study objectives

In individuals without raised blood pressure or raised cholesterol levels, but with a high incidence of cardiovascular disease because of their age, combination therapy with aspirin, antihypertensive drugs and a statin will reduce incidence of cardiovascular disease.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics committee of the Digestive Disease Research Centre, Tehran University of Medical Sciences, approved of this pilot study on 11 March 2006. Further ethical approval will be sought for a full study.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cardiovascular disease in middle-aged and older adults.

Interventions

Current interventions as of 08/09/2008:

A combination therapy (polypill) consisting of aspirin 81 mg, hydrochlorothiazide 12.5 mg, enalapril 2.5 mg and atorvastatin 20 mg or an identical placebo.

Please note that these amendments are due to the errors in the information provided at time of registration.

Previous interventions:

A combination therapy (polypill) consisting of aspirin 75 mg, hydrochlorothiazide 1.25 mg, enalapril 2.5 mg and atorvastatin 10 mg or an identical placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Aspirin, hydrochlorothiazide, enalapril and atorvastatin

Primary outcome(s)

Combined cardiovascular events (MI, new onset angina, coronary artery surgery, stroke or sudden cardiac death)

Key secondary outcome(s)

1. Total mortality
2. Gastrointestinal bleeding

Completion date

01/04/2008

Eligibility

Key inclusion criteria

1. Men between the ages of 50 and 80 (inclusive)
2. Women aged 55 to 80 (inclusive)
3. Living in Kalaleh
4. Free from existing cardiovascular disease (stroke, Transient Ischaemic Attack [TIA], Myocardial Infarction [MI], or angina)
5. Not currently be taking or eligible for antihypertensive treatment, aspirin or statins

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Total cholesterol levels exceed 240 mg/dL
2. Blood pressure exceeds 160/100 mmHg at baseline
3. People with existing vascular disease
4. Clear indication or contra-indication for any component of the polypill or other chronic medical problems that would interfere with participation

Date of first enrolment

01/10/2006

Date of final enrolment

01/04/2008

Locations

Countries of recruitment

United Kingdom

England

Iran

Study participating centre

Department of Public Health and Epidemiology

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

Ministry of Health and Medical Education (Iran)

ROR

<https://ror.org/01rs0ht88>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Digestive Disease Research Center, Tehran University of Medical Sciences (Iran)

Funder Name

Endocrine and Metabolic Reseach center, Tehran University of Medical Sciences (Iran)

Funder Name

Alborz daruo Pharmaceutical company (Iran)

Funder Name

Deputy for health, Iranian ministry of Health and Medical Education (Iran)

Results and Publications

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	01/08/2010		Yes	No