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Effect of a Polypill on middle-aged and elderly Iranians

Submission date 14/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/10/2006	**Overall study status** Completed	
Last Edited 04/10/2011	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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