Polypill Prevention Trial 1

Submission date	Recruitment status No longer recruiting	Prospectively registered		
11/02/2011		☐ Protocol		
Registration date 15/04/2011	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 24/09/2012	Condition category	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr David Wald

Contact details

Wolfson Institute of Preventive Medicine Chartehouse Square London United Kingdom EC1M 6BQ d.s.wald@qmul.ac.uk

Additional identifiers

Protocol serial number

PPT01

Study information

Scientific Title

A randomised placebo controlled double-blind cross-over trial of the Polypill on risk factor reduction

Acronym

PPT1

Study objectives

To determine the reduction in serum cholesterol and blood pressure using the polypill and to assess the prevalence of adverse effects

Ethics approval required

Old ethics approval format

Ethics approval(s)

North London Research Ethics Committee 1, approved on 29th September 2010, REC Ref: 10 /HO717/66

Study design

Randomised placebo-controlled double-blind cross-over trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cardiovascular Disease

Interventions

Polypill (containing simvastatin, losartan, amlodipine and hydrochlorothiazide) - Each treatment arm lasts 12 weeks and consists of polypill or placebo in random order, followed by a 2 year open label monitoring phase

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Simvastatin, losartan, amlodipine, hydrochlorothiazide

Primary outcome(s)

- 1. Serum cholesterol
- 2. Systolic blood pressure
- 3. Diastolic blood pressure

Outcomes assessed at the end of each 12 week treatment period

Key secondary outcome(s))

- 1. Adverse effects
- 2. Adherence

Completion date

05/07/2013

Eligibility

Key inclusion criteria

Men and women aged 50 and over, without selection on the basis of other risk factors, for whom there is no medical contra-indication to taking the Polypill

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

- 1. Clinical history of cardiovascular disease
- 2. Any illness judged to contra-indicate participation in the trial
- 3. Taking other specified drugs: lithium, cyclosporine or other calcineurin inhibitors, erythromycin or other macrolides, azole antifungals, ritonavir or other protease inhibitors, amiodarone

Date of first enrolment

05/01/2011

Date of final enrolment

05/07/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Wolfson Institute of Preventive Medicine
London
United Kingdom
EC1M 6BQ

Sponsor information

Organisation

Queen Mary University of London (UK)

ROR

https://ror.org/026zzn846

Funder(s)

Funder type

Charity

Funder Name

Barts and the London Charitable Foundation (UK)

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	01/05/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes