

# Polypill Prevention Trial 1

<b>Submission date</b> 11/02/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/04/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 24/09/2012	<b>Condition category</b> 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

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## 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**

Intentional

**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?
<a href="#">Results article</a>	results	01/05/2012		Yes	No