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Polypill Prevention Trial 1

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

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
Charterhouse Square
London
United Kingdom
EC1M 6BQ
d.s.wald@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
1. Serum cholesterol
2. Systolic blood pressure
3. Diastolic blood pressure
Outcomes assessed at the end of each 12 week treatment period

Secondary outcome measures
1. Adverse effects
2. Adherence

Overall study start date
05/01/2011

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

Age group
Senior

Sex
Both

Target number of participants
50-100

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
England

United Kingdom

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

Sponsor information

Organisation
Queen Mary University of London (UK)

Sponsor details
Queen Mary Innovation Centre
5 Walden Street
Whitechapel
London
England
United Kingdom
E1 2EF
gerry.leonard@bartsandthelondon.nhs.uk

Sponsor type
University/education

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Barts and the London Charitable Foundation (UK)

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	01/05/2012		Yes	No