

High blood pressure control and lipid lowering in patients at high cardiovascular risk: a cluster randomised factorial comparison of educational and protocol-based interventions to help primary care teams improve control of patients with poor risk factor control

Submission date 18/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 18/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 06/04/2017	Condition category Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

6727

Study information

Scientific Title

High blood pressure control and lipid lowering in patients at high cardiovascular risk: a cluster randomised factorial comparison of educational and protocol-based interventions to help primary care teams improve control of patients with poor risk factor control

Acronym

HiLo

Study objectives

This is a 2 x 2 factorial design complex health services intervention research trial which examines the influence of none, either or both of two interventions designed to help primary care clinicians improve the blood pressure and cholesterol control of patients at high risk of cardiovascular events over 12 months. One intervention explores expertise sharing whilst the other explores protocol adherence by clinicians.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Single-centre randomised interventional prevention, process of care and treatment trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Topic: Cardiovascular, Diabetes Research Network, Primary Care Research Network for England;
Subtopic: Both, Not Assigned, Cardiovascular (all Subtopics); Disease: Diabetic Control,
Cardiovascular, All Diseases

Interventions

1. Case management
 2. Protocol-based treatment suggestions
 3. Clinical educational support
 4. Expertise sharing
- Follow-up length: 12 months

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Change in blood pressure (BP) treatment at 1 year

Secondary outcome measures

1. Change in lipid treatment at 1 year
2. Change in systolic blood pressure (BP) at 1 year
3. Change in total cholesterol at 1 year

Overall study start date

01/06/2006

Completion date

01/08/2011

Eligibility**Key inclusion criteria**

1. Elevated systolic blood pressure greater than or equal to 160 mmHg within the last 12 months
2. Elevated total cholesterol greater than or equal to 5 mmol/l
3. Patients in secondary prevention, or risk equivalent, or hypertensives in primary prevention at more than 20% 10-year cardiovascular disease (CVD) risk by QRISK2 or Framingham equations
4. Male and female, lower age limit of 40 years

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned sample size: 10000; UK sample size: 10000

Key exclusion criteria

Compelling reasons to avoid increase in blood pressure or lipid-lowering medication, such as severe debilitating illness or terminal cancer

Date of first enrolment

01/06/2006

Date of final enrolment

01/08/2011

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Barts and The London NHS Trust

London

United Kingdom

EC1M 6BQ

Sponsor information**Organisation**

William Harvey Research Institute (UK)

Sponsor details

Barts and The London

Queen Mary's School of Medicine and Dentistry

Rutland Place

Charterhouse Square

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Sponsor type

Research organisation

Website

<http://www.whri.qmul.ac.uk/>

ROR

<https://ror.org/0574dzy90>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

City and Hackney Teaching Primary Care Trust (UK)

Funder Name

Merck Schering-Plough (UK)

Funder Name

Pfizer (UK)

Alternative Name(s)

Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Tower Hamlets Primary Care Trust (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