

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	☐ Prospectively registered
		☐ Protocol
Registration date 18/06/2010	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 06/04/2017	Condition category Circulatory System	☐ Individual participant data
		☐ 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

Protocol serial number

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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

Change in blood pressure (BP) treatment at 1 year

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre
Barts and The London NHS Trust
London
United Kingdom
EC1M 6BQ

Sponsor information

Organisation
William Harvey Research Institute (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, Pfizer Inc

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary