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Delivering enhanced cardiovascular disease and hypertension care through private health facilities in Pakistan

Submission date	**Recruitment status**	[_] Prospectively registered
28/05/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/07/2012	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/04/2014	Circulatory System	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Over 80% of cardiovascular deaths take place in low- and middle-income countries but despite convincing evidence that lowering of blood pressure decreases cardiovascular disease and death, the control of hypertension (high blood pressure) has been poor in developing countries for a variety of reasons. In Pakistan alone hypertension was shown to affect 18% of adults aged >15 years and around 33% of adults above 45 years. In addition to the high burden of the disease, the availability and quality of the first level care public facilities is not adequate, more so in urban areas. This makes private clinics and small hospitals an alternate choice for first level care in urban areas. However, in the absence of a regulatory and/or partnership mechanism, the care delivery practices vary widely. The proposed implementation research is to develop and evaluate a model of delivering a cardiovascular-hypertension care package through a network of private clinics led by the district, already engaged in communicable disease control activities in Pakistan. The aim is to enhance the delivery of quality cardiovascular-hypertension care through private health facilities in urban settings. The conditions to be covered in the care package include: hypertension, type 2 diabetes and hypercholesteremia (high blood cholesterol).

Who can participate?

All newly diagnosed hypertensive male and female patients aged 25 years or more from the catchment population of the respective facility will be included after an informed consent.

What does the study involve?

If you agree to take part your care records will be used to assess high blood pressure and associated illnesses management services at the clinic. You will attend twice for blood pressure monitoring, once at the start of study and once at the end of study. This monitoring of blood pressure will be free of charge and you will be provided with travel compensation.

What are the possible benefits and risks of participating?

Taking part is voluntary and you may choose not to take part or to stop being part of the study at any time. The care you receive will be the same irrespective of your participation in the research. If you take part you may have the usual or slightly different procedures (more

information/data will be taken if you take part in the project). There are no direct benefits to you, but this study hopes to improve the care of patients with high blood pressure and associated illnesses at private clinics in the country. You will help us find out the best way to care for patients like you in the future. There are no added risks involved in participating in this study.

Where is the study run from?
Pakistan with the involvement of the University of Leeds, UK.

When is the study starting and how long is it expected to run for?
The study started in January 2012 and will run until December 2016.

Who is funding the study?
University of Leeds, UK.

Who is the main contact?
Dr Amir Khan
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Delivering enhanced cardiovascular disease and hypertension care through private health facilities in Pakistan: a cluster randomized trial

Study objectives
The enabling of private health facilities for non-communicable disease intervention for adult hypertensive patients will improve the control of hypertension by decreasing mean systolic BP by at least 6mm Hg.
The enabling of private health facilities for non-communicable disease intervention for adult hypertensive patients will improve the control of blood glucose (HbA1C < 7.5 %) and serum cholesterol (<200mg/dl) by at least 15% (as compared to the current practice).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Leeds Research Ethics Committee, 20 March 2012, ref: HSLTLM11026
2. National Bioethics Committee, 30 April 2012, ref: BC:89

Study design
Pragmatic cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Hypertension / Cardiovascular Disease

Interventions
Intervention arm
Quality care will be delivered to adult hypertension patients, through enabled private healthcare facilities.
The inputs for delivering quality care will include:
1. Operational guidelines
2. Supplement equipment and communication
3. Training and supervisory support
4. Patient education materials

The care delivery dimensions to be addressed will include:
1. Enhanced screening and diagnosis
2. Standardized prescription
3. Interactive education of patient and family
4. Follow-up and adherence
5. Recording, reporting and monitoring
6. Referral linkage with respective district hospital
7. District health office engagement and support
8. Technical support for in-country research uptake

Control arm
The control for comparison is the current care practices (for hypertension and associated conditions) at the private health care facilities.
The only addition will be
1. Enhanced screening and diagnosis
2. Introduction of HTN-CVD register for collecting core data set on patients attending these control facilities.

In current practice, each practitioner manages HTN-CVD cases, as per his/her self-determined regimen and without reference to any specific guidelines and/or tools. The health staff at a facility will offer the same care package to all its HTN-CVD cases, regardless of their social strata and other preferences. This will reduce the chances of intra-cluster contamination as well as strengthen and simplify the implementation of prospective evaluation. All trial patients will be asked to arrange their prescribed drugs, so that the trial reflects the real life practice in private health care delivery system.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Measure the comparison is hypertension control. This outcome measure will be taken at the completion of 15 months of patient registration. The hypertension control at 15 months will be measured in terms of mean change in systolic blood pressure, i.e. change of mean blood pressure compared to the baseline. The blood pressure measurements at the registration and at completion of 15 months will be taken and recorded by an external expert assessor, not involved in trial implementation and also kept blind to the trial arms (with a mercury apparatus).

Secondary outcome measures
1. Glycaemic control
2. Cholesterol control and tobacco cessation among the registered hypertension patients

The glycaemic control and cholesterol control at 15 months will be measured in terms of mean change in HbA1c and change in serum cholesterol respectively. A recognized quality assured laboratory service will be used for HbA1c and serum cholesterol testing at the baseline and 15 months follow-up. In addition to these three key outcome measures, an additional set of process, output and outcome measures will also be selected, through TWG process, for comparing the intervention and control.

Overall study start date
01/01/2012

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. All newly diagnosed hypertensive (systolic blood pressure >140 mm Hg, diastolic blood pressure >90 mm Hg)
2. Male and female patients aged 25 years or more from the catchment population of the respective facility

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
A total of 912 patients in the trial. A total of twelve clusters (i.e. six clusters in each trial arm) will be included in the study, with a minimum of 76 patients recruitment in each cluster.

Key exclusion criteria
1. Pregnant women
2. Persons with advanced chronic disease
3. Person with conditions that cause secondary hypertension
4. Person with known history of hypertension and/or CVD treatment in the past
5. Person not likely to stay in the area for the required follow-up period of 15 months

Date of first enrolment
01/01/2012

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Pakistan

Study participating centre
Association for Social Development
Islamabad

Pakistan
44000

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
Leeds Institute of Health Sciences
COMDIS-HSD
Charles Thackrah Building
101 Clarendon Road
Leeds
England
United Kingdom
LS2 9LJ

Sponsor type
University/education

Website
http://www.leeds.ac.uk/hsphr/research/NCIHD/comdis-hsd.html

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
University/education

Funder Name
COMDIS-HSD - Research Programme Consortium, University of Leeds (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?
Protocol article	protocol	25/09/2013		Yes	No