

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

| | | |
|--|---|--|
| Submission date 28/05/2012 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 26/07/2012 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 24/04/2014 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

asd@asd.com.pk

Contact information

Type(s)

Scientific

Contact name

Dr Muhammad Amir Khan

Contact details

Association for Social Development

No. 12, Street 48, F-7/4

Islamabad

Pakistan

44000

+92 51 2611 231 33

asd@asd.com.pk

Additional identifiers

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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).

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |