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Strengthening the delivery of asthma and chronic obstructive pulmonary disease (COPD) care at primary health care facilities

Submission date
03/04/2013

Recruitment status
No longer recruiting

Registration date
30/05/2013

Overall study status
Completed

Last Edited
01/11/2019

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
We are carrying out a study for strengthening the delivery of asthma and chronic obstructive pulmonary disease (COPD) care at primary health care (PHC) facilities already supporting tuberculosis (TB) care in Pakistan. The aim is to deliver quality asthma and COPD care through primary health care facilities in Pakistan.

Who can participate?
The eligible asthma and COPD patients of both genders, aged eighteen and above in the catchment area of the given health facility will be recruited in the study. A total of 428 asthma and 306 COPD patients will be recruited .

What does the study involve?
The proposed study will help to improve access to and quality of care for common lung health conditions, especially in underserved population i.e. rural areas. This will be done mainly by developing, testing and refining packages of essential curative and preventive services for asthma and COPD, through primary health care. This covers both the delivery and management support dimensions of quality care. We will compare the control of asthma and COPD achieved in the patients receiving quality lung health care (i.e. using standardised evidence-based guideline and materials) in comparison with the disease control for those receiving routine care at the PHC facilities. The asthma control and COPD control will be measured at baseline (beginning of the study) and 6 and 12 months after the start of treatment. The proposed research on care of asthma and COPD conditions will cover: a) enhanced screening and diagnosis, b) standardized prescription, c) interactive education of patient and family, d) follow-up and adherence, e) referral linkage with respective district hospital, f) district health office engagement and support, and g) technical support for in-country research uptake.

What are the possible benefits and risks of participating?
Participants:
Free diagnosis and treatment as per standardized clinical guidelines: Though routine drugs for the asthma and COPD are mentioned in the Drug list of the primary health care facilities - Rural

Health Centre (RHC), they are not always present given the scarce resource setting. RHCs will be strengthened in this reference, to an extent possible, in the intervention arm.
The control arm patients will receive the current best practice, whereas intervention arm will receive enhanced care. Only nationally approved diagnostic and drugs will be used. The trial protocols will not expose patients to any additional risk.
Society:
Two districts with an estimated population of 2.5 million living in rural and semi-urban localities [including 18 RHCs and Tehsil headquarter hospitals (THQs)] will be enabled to manage and sustain quality care for asthma and COPD. These services will continue even after the trial, through respective district health office and potentially benefit thousands of diabetics in the district.
At least 214 asthma and 153 COPD cases (in the intervention arm) will receive enhanced lung care.
A set of case management desk guide, training package, patient education materials, and recording/reporting/monitoring system for lung health care will be potentially used in all 135 districts of Pakistan:
Sound scientific evidence for programmatic decision making in Pakistan (and elsewhere).
There are no adverse effects of the trial itself but there may be expected side effects of certain drugs that are used in the Asthma- COPD management package. To decrease this risk to the minimal only approved drugs will be used. The trial protocols will not expose patients to any additional risk.

Where is the study run from?
The study will run from 18 rural health centres (RHCs) and sub-district hospitals in districts Rawalpindi and Islamabad.

When is the study starting and how long is it expected to run for?
October 2012 to December 2016.

Who is funding the study?
The study is funded by COMDIS Health Service Delivery Research Programme Consortium (COMDIS-HSD), The University of Leeds UK and is being implemented by Association for Social Development in Pakistan.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Strengthening the delivery of asthma and chronic obstructive pulmonary disease (COPD) care at primary health care facilities - a randomised controlled trial in Pakistan

Study objectives
How effective and feasible is it to achieve better asthma and COPD control among adult patients (i.e. >18 years) attending the primary health care facilities already strengthened for Tuberculosis (TB) care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Leeds Research Ethics Committee, 22/01/2013, ref: HSLTLM/12/025
2. National Bioethics Committee, 20/03/2013, ref: 4-87/NBC-111/13/RDC/4682

Study design
Pragmatic cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

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
Asthma and Chronic Obstructive Pulmonary Disease (COPD)

Interventions
Intervention arm:
Quality care will be delivered to adult asthma and COPD patients, through enabled primary healthcare facilities already strengthened for TB care.
The inputs for delivering quality care will include:
1. Context sensitive case management and operational guidelines
2. Supplement equipment
3. Ensure un-interrupted supply of drugs
4. Training and supervisory support
5. Interactive patient education materials

The care delivery dimensions to be addresses will include:
1. Enhanced screening and diagnosis
2. Standardized prescription
3. Interactive education of patient and family
4. Follow up and adherence
5. Standardised 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 a routine set of activities for asthma and COPD case management at primary health care facilities. The only addition will be:
1. Introduction of standard diagnosis and recording practices for asthma/COPD patients attending these control facilities.
2. Continued provision of essential drugs (at current level), through the district health office.

The routine set of activities on the basis of early service review are:
1. Varied diagnostic and prescription practices, as per individual doctor.
2. Salbutamol, corticosteroids, and antibiotic tablet/injection are available, with occasional interruption.
3. Currently patients are provided with 2-3 day drugs.
4. Record keeping is limited to OPD register only.
5. Late patient retrieval is not currently practiced.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Asthma
The control of asthma is measured as Forced Expiratory Volume/Forced Vital Capacity (FEV1

/FVC) ratio > 0.75 in an individual patient.
Trained facility staff, at the start and then after 6 and 12 months of treatment, will assess the outcome in an individual patient.

2. COPD
The control of COPD is measured as the stable or an improved BODE index in an individual patient. The dimensions included are: Body Mass Index (BMI kg/m2), Obstruction (FEV1/FVC ratio), Dyspnoea (assessed on MRC scale), and Exercise capacity (6 minute walk). Trained facility staff, at the start and then after 6 and 12 months of treatment, will assess the index in an individual patient. The mean difference between intervention and control arms will be at least one score on BODE index.

Secondary outcome measures
1. Secondary outcome measures to indicate utilization and quality of asthma and COPD care will be selected, through Technical Work Group process, for comparing the intervention and control arms. The examples of such indicators to consider are complications, adherence, etc.
2. Another secondary outcome will be incremental cost effectiveness to manage asthma and COPD in intervention as compared to the control arms.

Overall study start date
01/10/2012

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. All newly diagnosed cases of asthma and COPD who have given the consent to participate in the trial
2. Male and female patients aged 18 years or more from the catchment population of the respective facility

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
A total of 428 asthma and 306 COPD patients will be recruited in 18 trial clusters (i.e. 24 and 17 patients/cluster respectively).

Key exclusion criteria

1. Persons less than 18 years old
2. Persons not giving consent for the study
3. Persons having contraindication for trial procedures (e.g. people not fit for 6 minute walk, advanced or complicated cases as per stage IV of National Institute for Health and Care Excellence (NICE) / Global Initiative for Chronic Obstructive Lung Disease (GOLD)]

Date of first enrolment
01/10/2012

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Pakistan

Study participating centre
Association for Social Development
Islamabad
Pakistan
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Sponsor information

Organisation
University of Leeds - COMDIS-HSD (UK)

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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	16/11/2015		Yes	No
Results article	COPD cohort results	20/03/2019	01/11/2019	Yes	No