Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Exploring the pharmacist's intervention for precluding the factors effecting medication adherence in Chronic Obstructive Pulmonary Diseases (COPD) following GOLD (Global Initiative for Chronic Obstructive Lungs diseases) guidelines in Pakistan

Protocol summary

Study aim
The aim of the study is to preclude the medication non-adherence in the COPD patients in Pakistan

Design
Study design: A single centered randomized controlled trial Study Groups: Interventional group, Controlled group sample size: 144 individuals (72 in each group)

Settings and conduct
The ongoing study is conducted by the the principle investigator in Holy family hospital, Rawalpindi, Pakistan

Participants/Inclusion and exclusion criteria
Inclusion criteria: COPD patients Exclusion criteria: patients suffering from all other diseases except COPD

Intervention groups
Single interventional group: The main reason for medication non-adherence is unawareness of the disease, medication, treatment and management of the disease. Education intervention is provided to the patients to improve medication adherence

Main outcome variables
Improved medication adherence in COPD patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220516054875N1**
Registration date: **2022-05-23, 1401/03/02**
Registration timing: **prospective**

Last update: **2022-05-23, 1401/03/02**
Update count: **0**

Registration date
2022-05-23, 1401/03/02

Registrant information

Name
Hafsa Kanwal

Name of organization / entity
Quaid-i-Azam university, Islamabad

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Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-01, 1401/03/11

Expected recruitment end date
2022-11-01, 1401/08/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Exploring the pharmacist's intervention for precluding the factors effecting medication adherence in Chronic Obstructive Pulmonary Diseases (COPD) following GOLD (Global Initiative for Chronic Obstructive Lungs diseases) guidelines in Pakistan

Public title
The role of pharmacist for enhancing medication adherence in COPD (Chronic Obstructive Pulmonary Diseases) patients in pakistan

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients only attend the outpatient COPD wards, confirmed diagnosis of COPD by the hospital consultant for at least 1 year Newly diagnosed patients with a forced expiratory volume in 1 s (FEV1) of 30–80% of the predicted normal value Patients that hospital consultant agree that the patient is suitable for entering the trial

Exclusion criteria:

Moderate to severe learning difficulties Mobility problems, confusion, disorientation or terminal illness Congestive heart failure or if they are attending a pulmonary rehabilitation programs consulting a pulmonary nurse or clinical pharmacist in the last 6 months

Age

From **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Individual patient enrolled in the study as 1:1 is included in Interventional Group and Control Group

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Rawalpindi Medical University, Rawalpindi, Pakistan

Street address

J329+WJ2, Tipu Rd, Chamanzar Colony

City

Rawalpindi

Postal code

46000

Approval date

2021-04-23, 1400/02/03

Ethics committee reference number

63/IREF\2021

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease (COPD)

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description

The medication adherence by pharmacist intervention will be improved

Timepoint

Before intervention, after 24 weeks of intervention

Method of measurement

Self-structured medication adherence Questionnaire will be filled to check the adherence level

Secondary outcomes

1

Description

Assessment of patient quality of life by St. George Respiratory Questionnare

Timepoint

Before intervention and after 24 weeks of intervention

Method of measurement

Patients interviews

Intervention groups

1

Description

Intervention group:

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Holy Family Hospital

Full name of responsible person

Prof. Dr. Muhammad Khurram

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Web page address
Grant name
Higher Education commission, Pakistan
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
HEC, indigenous scholarship
Proportion provided by this source
80
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Quaid-i-Azam university, islamabad
Full name of responsible person
Dr. Amjad Khan
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The data will be available after publication. And data will be displayed after statistical analysis so there is no need to display individual patient data

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Study patients demographics, results(primary outcomes, secondary outcomes) will be shared after once the data will be published

When the data will become available and for how long
After publishing data will be available for long

To whom data/document is available
Any researcher or healthcare team member from hospital or academia can ask for the data

Under which criteria data/document could be used
if someone is designing their own study or conducting this type of study

From where data/document is obtainable
e-mail ID = hkanwal@bs.qau.edu.pk

What processes are involved for a request to access data/document
requesting via email, and the data will be provided by the principle investigator

Comments
yes, the study is ongoing conducted but after reading your policy, I can start my study according to the plan after approval