

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Country

Pakistan

Phone

+92 51 90644128

Email address

hkanwal@bs.qau.edu.pk

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 Questionnaire

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

Street address

J329+WJ2, Tipu Rd, Chamanzar Colony

City

Rawalpindi

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46000

Phone

+92 51 9290755

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drmuhammadkhurram@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Quaid-i-Azam University , Islamabad

Full name of responsible person

Dr. Amjad Khan

Street address

department of pharmacy, Quaid-i-Azam university,
Islamabad, Pakistan

City

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Postal code

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Phone

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amjadkhan@qau.edu.pk

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

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Department of pharmacy, Quaid-i-azam university

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Islamabad

Province

Capital territory

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Email

amjadkhan@qua.edu.pk

Person responsible for scientific inquiries

Contact

Name of organization / entity

Quaid-i-Azam university, Islamabad

Full name of responsible person

Hafsa Kanwal

Position

Ph. D scholar

Latest degree

Master

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Hafsa Kanwal

Position

PhD scholar

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15320

Phone

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Fax

Email

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