

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of efficacy and safety of 7-days vonoprazan versus 14-days esomeprazole based triple therapy for H- pylori infection

Protocol summary

Study aim

To compare the effect of 7-days Vonoprazan based triple therapy and 14-days Esomeprazole based triple therapy on the stool antigen test conversion from (positive to negative) in H. pylori infection To compare the effect of 7-days Vonoprazan based triple therapy and 14-days Esomeprazole based triple therapy on improvement of clinical symptoms in H. pylori infection To compare the effect of 7-days Vonoprazan based triple therapy and 14-days Esomeprazole based triple therapy on occurrence of any adverse effects in H. pylori infection

Design

Open label Prospective randomized controlled trial

Settings and conduct

Department of gastroenterology tertiary care hospital
Rawalpindi Pakistan

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age above 18- years diagnosed for h-pylori by positive stool antigen test and Patients having symptoms of acid-peptic disease Both male and female patients nonpregnant females Exclusion criteria: Patient with history of drug allergy to either esomeprazole, Vonoprazan, penicillin's or levofloxacin Previous h-pylori eradication therapy Pregnant and breast-feeding mothers Patient with serious CVS, liver, renal, pulmonary disorders, or acute malignancy History of gastric malignancy or surgery History of drug abuse History of using anti-biotics that affect h-pylori with in 4weeks

Intervention groups

Intervention group B: Vonoprazan 20mg BD based triple therapy with levofloxacin for 7 days Control group A: Esomeprazole 20 mg BD based triple therapy with levofloxacin for 14 days

Main outcome variables

1. Conversion of stool antigen test from positive to negative
2. Clinical symptoms (dyspepsia) improvements
3. Antibiotic related adverse effects
4. Compliance of patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221207056738N1**

Registration date: **2022-12-28, 1401/10/07**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-28, 1401/10/07**

Update count: **0**

Registration date

2022-12-28, 1401/10/07

Registrant information

Name

farzana waqar

Name of organization / entity

National university of medical sciences Rawalpindi

Country

Pakistan

Phone

+92 51 4251022

Email address

drfaru11@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-20, 1401/09/29

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and safety of 7-days vonoprazan versus 14-days esomeprazole based triple therapy for H-pylori infection

Public title

Role of Vonaprazan in H.Pylori eradication

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Positive stool antigen test for h-pylori, endoscopic histopathological evidence of h-pylori. Age 18 years and above Both male and female patients presented with symptoms of dyspeps

Exclusion criteria:

Patient with history of drug allergy to either Pantoprazole, Vonoprazan Vonoprazan, penicillin's or clarithromycin , Previous h-pylori eradication therapy, Pregnant and breast-feeding mothers, Patient with serious CVS, liver, renal, pulmonary disorders or acute malignancy, ,History of gastric malignancy or surgery, History of drug abuse. History of using anti-biotics that affect h-pylori with in 4 weeks

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **122**

Randomization (investigator's opinion)

Randomized

Randomization description

Patient fulfilling inclusion criteria and after giving informed consent will be included study Method of randomization will be blocks generated by computer generated software Unit of randomization will be individual there will be no stratification of data Tools used in randomization will be www.randomize.net/Algorithms.HTML The random sequence of block will be built in 1:1 parallel number Allocation concealment will not be carried out

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

there will be two groups of participants each group will contain 61 patients. one group will take 14-days triple therapy with esomeprazole 20mg BD, levofloxacin 500mg OD, amoxicillin 1000mg BD and the second group will take 7-days triple therapy with vonoprazan 20mg BD, levofloxacin 500mg OD, amoxicillin 1000mg BD. adverse effect of both therapies will be assessed at day -3 and day-14 through telephone. stool antigen test will be

repeated after 28 days of the therapy

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional review committee

Street address

The mall parking lot, abid majeed road Rawalpindi Punjab

City

Rawalpindi

Postal code

44000

Approval date

2022-11-22, 1401/09/01

Ethics committee reference number

ERC/ID/233

Health conditions studied**1****Description of health condition studied**

Helicobacter pylori infection is a condition in which gram -ve bacteria called H- pylori reside in mucus lining of stomach lead to gastritis, ulcer manifest in the form of dyspepsia

ICD-10 code

B96.81

ICD-10 code description

Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

Primary outcomes**1****Description**

Conversion of stool antigen from positive to negative

Timepoint

After 4 weeks after the therapy

Method of measurement

Lab investigation. clinical assessment for symptoms improvement and side effects

Secondary outcomes**1****Description**

Improvement of clinical symptoms, side effects ,drug compliance, tolerability

Timepoint

2 and 4 weeks after intervention

Method of measurement

Through telephone and after 4 weeks at hospital OPD

Intervention groups**1****Description**

Intervention group: group 2 is the interventional group to which 7-days vonoprazan based triple therapy, new drug regimen, vonoprazan 20mg BD, amoxicillin 1000mg BD, levofloxacin 500mg OD for 7-days will be given.

Category

Treatment - Drugs

2**Description**

Control group: Control group 1 in which 14-days esomeprazole based conventional triple therapy with esomeprazole 20mg BD, amoxicillin 1000mg BD, levofloxacin 500mg OD for 14-days will be given

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Department of gastroenterology tertiary care hospital rawalpindi

Full name of responsible person

Farzana Waqar

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

National university of Medical Sciences Rawalpindi

Full name of responsible person

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Grant name

research grant for post graduate trainee

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

National university of Medical Sciences Rawalpindi

Proportion provided by this source

100

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**

National University of Medical Sciences Rawalpindi

Full name of responsible person

Farzana Waqar

Position

Post Graduate Trainee

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

NUMS

Full name of responsible person

Farzana Waqar

Position

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Latest degree

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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
statistical analysis, results and conclusions of the study
will be available online
When the data will become available and for how long
After completion of data collection. approximately by
March 2023
To whom data/document is available
Data will be kept safe with the principal investigator
Under which criteria data/document could be used
Through data sheets
From where data/document is obtainable
drfaru11@gmail.com
What processes are involved for a request to access data/document
Contact the principal Invetigator
Comments
not applicable