Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 bsed triple thrapy 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, vonoprazn 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 rawapindi
Full name of responsible person
Farzana Waqar
Street address
The Mall,parking lot,Abid Majeed road Rawalpindi Punjab
City
Rawalpindi
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44000
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+92 332 5881278
Email
drfaru11@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
National university of Medical Sciences Rawalpindi
Full name of responsible person
Dr Mudassar Noor
Street address
25 b, RR camp Rawalpindi
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Rawalpindi
Postal code
44000
Phone
+92 333 3693588
Email
smillingdr@yahoo.com
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

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NUMS
Full name of responsible person
Farzana Waqar
Position
Post Graduate Trainee
Latest degree

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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