Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of low dose and high dose of furazolidone in the treatment of Helicobacter pylori infection

Protocol summary

Study aim

Comparison of two regimens containing low dose and a high dose of Furazolidone in the treatment of Helicobacter pylori

Design

his study is a randomized clinical trial (Randomized Clinical Trial) study. Which was conducted in 2016-17 13 and includes patients with peptic ulcer referring to Shahid Sayyad Shirazi Hospital in Gorgan. In this clinical trial study, the study samples were randomly selected from patients with peptic ulcer referring to Shahid Sayyid Shirazi Hospital in Gorgan, which are confirmed by endoscopic examination of the upper digestive system and rapid urease test in Helicobacter pylori infection. Will be selected.

Settings and conduct

This study is a randomized clinical trial (Randomized Clinical Trial) study. Which was conducted in 2016-17 13 and includes patients with peptic ulcer referring to Shahid Sayyad Shirazi Hospital in Gorgan.

Participants/Inclusion and exclusion criteria

Criteria for entering the study include peptic ulcer with endoscopic diagnosis and proof of Helicobacter pylori infection with RUT test and consent to cooperation. Outcome criteria include pregnancy, cancer and liver and kidney failure, diabetes mellitus, history of NSAIDs, PPI, bismuth and antibiotics over the past 4 weeks, history of smoking and alcohol, and history of drug sensitivity.

Intervention groups

Group A: Low-dose OfAB treatment containing: Amoxicillin mg-BD 1000, Furazolidone mg-BD 100, Omeprazole mg-BD20, and Bismuth sub-citrate mg-BD 240 for 2 weeks B-Group II: High-dose OFAB treatment including: Amoxicillin mg-BD 1000, Furazolidone mg-BD 200, Umperazole mg-BD20 and Bismuth subitrate mg-BD 240 for 2 weeks

Main outcome variables

Reduce side effects; discontinue treatment

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20160118026097N6**
Registration date: **2021-05-11, 1400/02/21**
Registration timing: **retrospective**

Last update: **2021-05-11, 1400/02/21**
Update count: **0**

Registration date

2021-05-11, 1400/02/21

Registrant information

Name

Jamshid Vafaeemanesh

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 252931933

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j.vafaeemanesh@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

2016-07-22, 1395/05/01

Actual recruitment end date

2018-01-21, 1396/11/01

Trial completion date

2018-06-22, 1397/04/01

Scientific title
Comparison of low dose and high dose of furazolidone in the treatment of Helicobacter pylori infection

Public title
Comparison of low dose and high dose of furazolidone in the treatment of Helicobacter pylori infection
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Peptic ulcer diagnosis with endoscopic diagnosis test Helicobacter pylori infection with RUT consent to cooperate
Exclusion criteria:
Pregnancy Cancer or Liver Failure Diabetes Mellitus History of Cigarette History of Alcohol History of Drug Sensitivity
Age
From **18 years** old to **100 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **170**
Actual sample size reached: **170**
Randomization (investigator's opinion)
Randomized
Randomization description
This study will be performed by a random sampling method, block allocation. In such a way that In this study, 60 patients with corona will be randomly divided into two groups. The selection of groups will be based on the fact that individuals will be assigned to groups based on block randomization. Block size 4 is considered. So we have six blocks of four, ABAB, ABBA, AABB, BAAB BBAA, BABA. The selection of each block will also be random and will be done using dice. For example, if the number 5 comes in the dice roll, the AABB block is considered and Therefore, the first two patients are assigned to treatment A, and the two patients are then assigned to treatment B.The dice will be thrown ten times to complete the allocation of patients to treatment groups. Treatment with dexamethasone and control will also be based on accident (coin toss).
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
Golestan University of Medical Sciences
Street address
Golestan Research Center of Gastroenterology and Hepatology-GRCGH (GOUMS), Golestan University of Medical Sciences, Gorgan, Iran
City
gorgan
Province
Golestan
Postal code
01732430319
Approval date
2015-06-22, 1394/04/01
Ethics committee reference number
IR.GOUMS.REC.1394.135

Health conditions studied

1

Description of health condition studied
Helicobacterpylori Eradication
ICD-10 code
K25
ICD-10 code description
Gastric ulcer

Primary outcomes

1

Description
Response to treatment-Helicobacter pylori eradication after drug treatment with urease respiratory test
Timepoint
Six weeks after drug treatment
Method of measurement
Urease Respiratory Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: After obtaining informed consent and full explanation of the treatment process to the patient and his companions regarding the treatment process, under low-dose four-drug treatment (OfAB) including amoxicillin mg-BD 1000, furazolidone mg-BD 100, omeprazole mg-BD20, and bismuth 240 mg-BD subcitrate for 2 weeks.
Category

Treatment - Drugs

2

Description
Intervention group 2: After obtaining informed consent and full explanation of the treatment process to the patient and his companions about the treatment process, under treatment with four high-dose drugs (OFAB) including: amoxicillin mg-BD 1000, furazolidone mg-BD 200, omeprazole mg-BD20 and bismuth sub-citrate 240 mg-BD for 2 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sayyad Shirazi Educational Therapy in Gorgan
Full name of responsible person
vafaeimanesh jamshid
Street address
Shahid Sayyad Shirazi Educational Therapy in Gorgan
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4934174515
Phone
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Email
jvafaeemanesh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
hosein momeni
Street address
Gorgan - At the beginning of Sixta Kola Road, a complex of philosophical higher education
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gorgan
Province
Golestan
Postal code
79142-49361
Phone
+98 17 3230 3988
Email
h.momeni@gu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gorgan University of Medical Sciences
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
Ghoum University of Medical Sciences
Full name of responsible person
jamshid vafaeemanesh
Position
asAssociate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available