Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of based_furazolidone quadruple regimens in comparision with based_claritromycine for eradication of Helicobacter pylori

Protocol summary

Study aim
To compare the effectiveness of furazolidone_based quadruple therapy with claritromycine _based quadruple therapy in eradication of H pylori
Design
Randomized control trial, parallel group, double blind
Settings and conduct
One group receive quadruple regimen with furazolidone_based and another group receive claritromycine_based Blinding: patients: lack of knowledge about the type of regimens that receive Investigator: lack of knowledge about the type of patient`s regimens
Participants/Inclusion and exclusion criteria
Inclusion critria: Patients with peptic ulcer, dyspepsia, Gastritis ; with confirmation H pylori Age more than 18 Exclusin critria: age lesser than 18
Intervention groups
One group receive quadruple regimen with furazolidone_based and another group receive quadruple regimen with claritromycine_based
Main outcome variables
Determine the response of H pylori treatment

General information

Reason for update
Acronym
H pylori (Helicobacter pylori)
IRCT registration information
IRCT registration number: **IRCT20171203037734N1**
Registration date: **2018-06-10, 1397/03/20**
Registration timing: **prospective**

Last update: **2018-06-10, 1397/03/20**
Update count: **0**
Registration date
2018-06-10, 1397/03/20

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-11-01, 1397/08/10
Expected recruitment end date
2019-11-01, 1398/08/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of based_furazolidone quadruple regimens in comparision with based_claritromycine for eradication of Helicobacter pylori

Public title
Evaluation of two type of quadruple regimens of Helicobacter Pylori
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with peptic ulcer, dyspepsia, Gastritis with confirmation H pylori Age more than 18
Exclusion criteria:
Age lesser than 18

Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **194**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple, individual, computer software
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients: lack of knowledge about the type of regimens that receive Investigator: lack of knowledge about the type of patient`s regimens
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Joundishapoor university of medical science
Street address
Ahvaz, Golestan Blvd
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2018-05-05, 1397/02/15
Ethics committee reference number
IR.AJUMS.REC.1397.070

Health conditions studied

1

Description of health condition studied
H pylori eradication
ICD-10 code
B96.81
ICD-10 code description
Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

Primary outcomes

1

Description
Rate of H pylori eradication
Timepoint
Four weeks after treatment
Method of measurement
Urea breath test(UBT)

Secondary outcomes

1

Description
Side effect
Timepoint
Four weeks after treatment
Method of measurement
Patient's comments and examination by physician

Intervention groups

1

Description
Intervention group: (n=97) will receive furazolidone_based quadruple therapy (furazolidone 100 mg BD, Bismuth subcitrate 240 mg BD, Pantoprazole 40 mg BD, Amoxicilline 1000mg BD)
Category
Treatment - Drugs

2

Description
Control group: (n=97) will receive claritromycine_based quadruple therapy(claritromycine 500 mg BD, Bismuth subcitrate 240 mg BD, Pantoprazole 40 mg BD, Amoxicilline 1000 mg BD)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvax Imam khomini Hospital
Full name of responsible person
Pejman Alavinejad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Ahvaz, Golestan Blvd، Deputy of research and technology of Ahvaz Jondishapour University of Medical Science
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Ahvaz Jondishapour University of Medical Science
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
Ahvaz University of Medical Sciences
Full name of responsible person
Pejman Alavinejad
Position
Assistant professor
Latest degree
Subspecialist
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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
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
IPD collected for primary outcome measure only
When the data will become available and for how long
Starting 10 months after publication
To whom data/document is available
For people working in academic institutions
Under which criteria data/document could be used
No critria
From where data/document is obtainable
Lajmirnia.m@ajums.ac.ir Lajmirnia maryam
What processes are involved for a request to access data/document
At least 2 months after receiving their Email
Comments