Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of Quadruple and Triple Furazolidone Containing Regimens on Eradication of Helicobacter Pylori ,in Patients with Helicobacter pylori Infected Duodenal Ulcer , Gastric Ulcer and/or Erosive Gastrodeudinitis .

Protocol summary

Summary

The aim of this study is to evaluate safety and efficacy of ten days quadruple and triple furazolidone- based regimen in eradication of Helicobacter pylori. 372 H-pylori infected patients with proven peptic ulcer , duodenal and /or gastric erosions by endoscopy will be randomized into three groups: group A(OABF) with furazolidone (F) (200 mg bid);groupB(OABM-F); metronidazole (M) (500 mg bid) for the first5 days, followed by furazolidone (F) (200 mg Bid) for the second 5 days; group C(OAF) with furazolidone (F) (200 mg Tid).Duration of all eradication regimens will be ten days.Two months after treatment, a C14-urea breath test will be performed.Analysis of eradication rates will be done by intention-to-treat and per-protocol methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013120715701N1**
Registration date: **2013-12-31, 1392/10/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-12-31, 1392/10/10

Registrant information

Name

Marjan Mokhtare

Name of organization / entity

Mazandaran university of medical scienses,Imam Khomeini Hospital

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2012-06-01, 1391/03/12

Expected recruitment end date

2013-01-30, 1391/11/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Quadruple and Triple Furazolidone Containing Regimens on Eradication of Helicobacter Pylori ,in Patients with Helicobacter pylori Infected Duodenal Ulcer , Gastric Ulcer and/or Erosive Gastrodeudinitis .

Public title

Furazolidone Containing Regimens in Eradication of Helicobacter Pylori

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Helicobacter pylori infected duodenal ulcer; gastric ulcer;Gastric Erosion ;Deudenal Erosion;Age >18 year old. Exclusion criteria :pregnancy ;lactation ; history of previous H.pylori eradication ; taking antibiotics and/or bismuth and/or non-steroidal anti inflammatory drugs during the previous four weeks;

concomitant use of anticoagulant or corticosteroid;consuming substantial amounts of alcohol;,history of gastric surgery; significant underlying disease such as; liver;,renal; pulmonary; cardiac disease and neoplasms ; G6PD deficiency ;history of drug allergy to any medication in this study. .

Age
From **18 years** old to **83 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **372**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Mazandaran University of Medical Sciences and Health Services

Street address
Joybar 3 WAY ,Imam Sq,

City
Sari

Postal code

Approval date
2012-11-07, 1391/08/17

Ethics committee reference number
91-139

Health conditions studied

1

Description of health condition studied
Peptic Ulcer Disease(H.Pylori Eradication)

ICD-10 code
K25,K26, K

ICD-10 code description
Gastric ulcer, Duodenal ulcer, Gastritis,unspecified ,Duodenitis

Primary outcomes

1

Description
Helicobacter.pylori eradication rate

Timepoint
2 months after the completion of treatment courser

Method of measurement
Urea Breath Test

Secondary outcomes

1

Description
Adverse effect of Drugs

Timepoint
Daily recording during and after the treatment course

Method of measurement
Medical history and record sheet

Intervention groups

1

Description
Intervention group:triple therapy including ,omperazol 20 mg Bid,amoxycillin 1 gr Bid and furazolidone 200 mg Tid , all of them for 10 days

Category
Treatment - Drugs

2

Description
Intervention group 1:quadrapl therapy including, omperazol 20 mg Bid,amoxycillin 1gr Bid,bismuth 240 mg Bid and furazolidone 200 mg Bid ,all of them for 10 days

Category
Treatment - Drugs

3

Description
Intervention group 2:quadrapl sequential therapy including; omperazol 20 mg Bid,amoxycillin 1 gr Bid and bismuth 240 mg Bid ,all of them for 10 days.Metronidazol 500 mg Bid for first 5 days and then furazolidone 200 mg Bid for second 5 days.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person

Dr .Marjan Mokhtare

Street address

Razi Street

City

Sari

2

Recruitment center

Name of recruitment center

Tooba Clinic

Full name of responsible person

Dr.Vahid Hoseini ,Gastroenterologist

Street address

City

Sari

3

Recruitment center

Name of recruitment center

Gastroenterologists office or clinic

Full name of responsible person

Dr.Marjan Mokhtare

Street address

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mazandaran university of medical scienses

Full name of responsible person

Dr.Ahmadali Enayati

Street address

Moallem Square, Assistance of researches and technology

City

Sari

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research, Mazandaran university of medical scienses

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Scienses

Full name of responsible person

Marjan Mokhtare

Position

MD,Gastroenterologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty