Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Comparison of Levofloxacin-containing quadruple therapy versus standard triple therapy as the first line for the helicobacter pylori eradication

Protocol summary

Study aim

Comparison of Levofloxacin-containing quadruple therapy versus standard triple therapy as the first line for the helicobacter pylori eradication

Design

In this study, 98 eligible patients referring to the gastroenterology clinic of Mohammad Vasei Sabzevar Hospital are chosen purposefully. Sampling method is done nonprobability. Then, specimens are divided every other into two control and intervention groups.

Settings and conduct

Failed primary anti-Helicobacter pylori therapy results in a high rate of antimicrobial resistance. This necessitates a search for new regimens to cure H. pylori infection. In this study, 98 eligible patients referring to the gastroenterology clinic of Mohammad Vasei Sabzevar Hospital, after performing upper endoscopy and positive urease test are chosen purposefully. Sampling is done nonprobability. Then, specimens are divided every other into two control and intervention groups. Control group will be treated by Levofloxacin 500 mg bid, Bismuth 240 mg qid, Amoxicillin 1 gr bid and Pantoprazole 40 mg bid for 2 weeks. Also intervention group will be treated by Clarithromycin 500 mg bid, Amoxicillin 1 gr bid and Pantoprazole 40 mg bid for 2 weeks. The eradication will be verified 3 weeks after the completion of treatment by stool antigen test.

Participants/Inclusion and exclusion criteria

Inclusion criteria to this study: Patients who are performed upper endoscopy and have positive rapid urease test; over 18 years of age. Exclusion criteria from this study: Pregnancy; Allergy to medicine which used in this study; Patients were treated helicobacter pylori eradication previously

Intervention groups

Specimens are divided into two control and intervention groups. Control group will be treated by Levofloxacin 500 mg bid, Bismuth 240 mg qid, Amoxicillin 1 gr bid and Pantoprazole 40 mg bid for 2 weeks and Intevatoin group will be treated by Clarithromycin 500 mg bid, Amoxicillin 1 gr bid and Pantoprazole 40 mg bid for 2 weeks. The eradication will be verified 3 weeks after the completion of treatment by stool antigen test.

Main outcome variables

Main outcome of study will be comparison of Levofloxacin-containing quadruple therapy versus standard triple therapy as the first line for the helicobacter pylori eradication.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171112037420N1**
Registration date: **2018-01-03, 1396/10/13**
Registration timing: **retrospective**

Last update: **2018-01-03, 1396/10/13**
Update count: **0**

Registration date

2018-01-03, 1396/10/13

Registrant information

Name

Salehe Eydi

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 4724 4707

Email address

eydis88@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source
Sabzevar University of Medical Sciences

Expected recruitment start date
2017-06-13, 1396/03/23

Expected recruitment end date
2017-10-22, 1396/07/30

Actual recruitment start date
2017-06-13, 1396/03/23

Actual recruitment end date
2017-10-22, 1396/07/30

Trial completion date
empty

Scientific title
Comparison of Levofloxacin-containing quadruple therapy versus standard triple therapy as the first line for the helicobacter pylori eradication

Public title
Comparison of Levofloxacin based quadruple therapy with standard treatment in eradication of helicobacter pylori as first line Therapy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who are performed upper endoscopy and have positive rapid urease test. Patients with over 18 years of age

Exclusion criteria:
Pregnancy Allergy to medicent which used this study Patients were treated helicobacter pylori eradication previously. lack of willingness to continue the period of treatment lack of willingness to complete the period of treatment

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **98**
Actual sample size reached: **91**

Randomization (investigator's opinion)
Not 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
Ethics Committee of Sabzevar University of Medical Sciences and Health Services

Street address
Central Organization of Medical Sciences, Asad Abadi Street, sabzevar

City
sabzevar

Province
Razavi Khorasan

Postal code
9613873136

Approval date
2017-06-12, 1396/03/22

Ethics committee reference number
IR.MEDSAB.REC.1396.21

Health conditions studied

1

Description of health condition studied
Helicobacter Pylori infection

ICD-10 code
B98.0

ICD-10 code description
Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

Primary outcomes

1

Description
Eradication of Helicobacter Pylori infection

Timepoint
3 weeks after the completion of treatment

Method of measurement
Helicobacter pylori stool antigen test

Secondary outcomes

1

Description
Diarrhea

Timepoint
During the period of treatment

Method of measurement
Questionnaire

2

Description
Nausea
Timepoint
During the period of treatment
Method of measurement
Questionnaire

3

Description
Headache
Timepoint
During the period of treatment
Method of measurement
Questionnaire

4

Description
Hiccups
Timepoint
During the period of treatment
Method of measurement
Questionnaire

5

Description
Skin rash
Timepoint
During the period of treatment
Method of measurement
Questionnaire

6

Description
Papilation
Timepoint
During the period of treatment
Method of measurement
Questionnaire

7

Description
Bitter taste
Timepoint
During the period of treatment
Method of measurement
Questionnaire

8

Description
Neuropathic pain
Timepoint
During the period of treatment
Method of measurement
Questionnaire

9

Description
Constipation
Timepoint
During the period of treatment
Method of measurement
Questionnaire

10

Description
Chest stress
Timepoint
During the period of treatment
Method of measurement
Questionnaire

11

Description
Vometting
Timepoint
During the period of treatment
Method of measurement
Questionnaire

Intervention groups

1

Description
Control group: Levofloxacin-containing quadruple therapy (Levofloxacin 500 mg bid, Bismuth 240 mg qid, Amoxicillin 1 gr bid and Pantoprazole 40 mg bid) for 2 weeks
Category
Treatment - Drugs

2

Description
Intervention group: standard triple therapy (Clarithromycin 500 mg bid, Amoxicillin 1 gr bid, Pantoprazole 40 mg bid) for 2 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mohammad Vasei Hospital in Sabzevar
Full name of responsible person
دکتر مهدی مولوی
Street address
Opposite Health Park, Nuclear Martyrs Boulevard
City
Sabzevar
Province
Razavi Khorasan

Postal code
9613873136
Phone
+98 51 4401 1000
Email
info@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Ms. Elham Bashtani
Street address
Vice Chancellor for research, near to trooper, sabzevar
City
Sabzevar
Province
Razavi Khorasan
Postal code
9613873136
Phone
+98 51 4426 4462
Email
info@medsab.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice chancellor for research, Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
M.s Salehe Eydi
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Central Organization of Medical Sciences, Asad Abadi Street, sabzevar
City
Sabzevar
Province
Razavi Khorasan
Postal code
9613873136
Phone
+98 51 4401 1000
Fax
Email
info@medsab.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Dr. Mehdi Molavi
Position
Gastroenterologist
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Central Organization of Medical Sciences, Asad Abadi Street, Sabzevar
City
Sabzevar
Province
Razavi Khorasan
Postal code
9613873136
Phone
+98 51 4401 1000
Fax
Email
info@medsab.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
M.s Salehe Eydi
Position
medical student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Central Organization of the University of Medical Sciences, Asad Abadi Street, sabzevar

City
Sabzevar
Province
Razavi Khorasan
Postal code
9613873136
Phone
+98 51 4724 4707
Fax
Email
EydiS88@medsab.ac.ir
Web page address

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