

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

A comparison between sequential therapy versus standard quadruple therapy for *Helicobacter pylori* eradication in patients attended to firoozgar and rasul hospitals

Protocol summary

Summary

Due to the progressive decline in the usefulness of traditional diets, new approaches to treatment of *H.pylori* has been proposed. A promising approach is the sequential regimen (sequential). Side two treatment regimens. The main objectives of the project: the sequential regimen and standard four drug regimen will be compared in *Helicobacter pylori* eradication. Randomly divided into two groups of patients. For one of two groups of quadruple therapy and sequential therapy for other begins. 4 drug regimen consisting of omeprazole, amoxicillin, clarithromycin, is bismuth. Sequential regimen consisting of two stages. Step 1: 7 days of treatment with omeprazole + amoxicillin. Step 2: 7 days omeprazole + clarithromycin + Fvrazvlydn 8 weeks after treatment for eradication UBT test is called and then the two groups are compared. Exclusion criteria for the study of allergy to antibiotics. The total sample size of $n = 160$

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112288546N1**
Registration date: **2012-04-07, 1391/01/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-04-07, 1391/01/19

Registrant information

Name

Siamak Khaleghi

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2012-11-20, 1391/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between sequential therapy versus standard quadruple therapy for *Helicobacter pylori* eradication in patients attended to firoozgar and rasul hospitals

Public title

Sequential regimens in the treatment of *Helicobacter pylori*

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria is confirming the diagnosis of *H. pylori* infection by RUT or histology. Exclusion criteria for this study is allergy to antibiotics.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **160****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences Ethics Committee

Street address

class 5,tehran university building, ghods street,,keshavarz Boulevard,tehran

City

Tehran

Postal code

1417613151

Approval date

2011-08-24, 1390/06/02

Ethics committee reference number

867/130/90/3

Health conditions studied**1****Description of health condition studied**

Indigestion

ICD-10 code

K30

ICD-10 code description

Dyspepsia

Primary outcomes**1****Description**

Response to treatment

Timepoint

8 weeks after treatment.

Method of measurement

UBT test

Secondary outcomes**1****Description**

Intensity and pattern of gastritis

Timepoint

Before treatment

Method of measurement

Observed on endoscopy

2**Description**

Smoking

Timepoint

Baseline

Method of measurement

Pack /year, The question of the individual

3**Description**

Body mass index

Timepoint

Baseline

Method of measurement

Kg/m2, With scales and meters

Intervention groups**1****Description**

patients randomly divided into two groups . quadruple therapy for control group was began. 4 drug regimen consisting of omeprazole (20mg BID), amoxicillin 1gr BID)), clarithromycin (500mg BID), is bismuth.

Category

Treatment - Drugs

2**Description**

sequential therapy for case group was began. Sequential regimen consisting of two stages. Step 1: 7 days of treatment with omeprazole (20mg BID) + amoxicillin (1gr BID) is. Step 2: 7 days of omeprazole (20mg BID + Fvrazvlydn (100mg BID) + clarithromycin 500mg BID)) 8 weeks after treatment for eradication UBT test is called and then the two groups are compared

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool akram hospital

Full name of responsible person

Dr.Siamak khaleghi

Street address**City**

Tehran

2

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person**Street address****City**

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Tehran University of medical sciences

Full name of responsible person

Ms. Malmir

Street address

Room 505,Floor 5,ghods st., Keshavarz Blvd, Tehran University of Medical Sciences, Tehran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Deputy of Tehran University of medical sciences

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

Rasool Akram Hospital

Full name of responsible person

Dr. Saideh Naghibi

Position

MD, Internist

Other areas of specialty/work**Street address**

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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