Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

A clinical trial to compare the effect of high dose zinc sulphate and placebo on ulcer size of patients with peptic and jejunal ulcer

Protocol summary

Summary

So far, specific dose of zinc sulphate for peptic ulcer healing has not been proved in any study. In the only study conducted in Iran, certain outcome has not been achieved and just increasing the dose of zinc sulfate is recommended. This study wants to determine the effect of high doses of zinc sulfate on peptic and jejunal ulcer. A total of 90 patients who were admitted to the endoscopy clinic of gastrointestinal department of Sanandaj Tohid Hospital and fulfilled the inclusion criteria randomly divided into two intervention and control groups using block randomization with block sizes of 4. Patients and researcher were unaware of the grouping. Presence of peptic and jejunal ulcer in these patients has been proved by subspecialist of gastroenterology via endoscopy. Ulcer size was determined by subspecialist of gastroenterology via endoscopy unit. Patients and researcher were unaware of the grouping. Inclusion criteria was presence of peptic ulcer during endoscopy and exclusion criteria were presence of clear symptoms indicating malignancy in observation, evidence of ulcer malignancy in pathology result, patient reluctance to endoscopy, patients reluctance to continue taking drugs, drug discontinuation more than two days, diseases that impair absorption (cirrhosis, celiac disease). In the intervention group zinc sulfate 220 mg capsules (Alhavi Pharmaceutical Company) gave to patients daily and in control group patients take placebo. Both the drug and placebo were in the same packages and gave to patients by clinic nurse who is aware of patient grouping. Patients` phone number was taken and to ensure that patients taking zinc sulfate telephone follow-up was performed weekly.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014062212789N4**

Registration date: **2014-10-06, 1393/07/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-10-06, 1393/07/14

Registrant information

Name

Masoud Rasolabady

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Kurdistan University of Medical Sciences

Expected recruitment start date

2014-07-06, 1393/04/15

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effect of high dose zinc sulphate and placebo on ulcer size of patients with peptic and jejunal ulcer

Public title
Effect of zinc sulphate on peptic and jejunal ulcer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: presence of peptic ulcer during endoscopy Exclusion criteria: presence of clear symptoms indicating malignancy in observation, presence of malignancy in pathology, patient reluctance to endoscopy, unwillingness to continuing to use the drug, drug discontinuation more than two days, diseases that impair absorption (cirrhosis, celiac disease).
Age
From **16 years** old to **85 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
If RUT test is positive triple therapy including amoxicillin, clarithromycin, omeprazole is prescribed for two weeks. According to ulcer size (greater than or equal to three centimeters or smaller than three centimeters) treatment time is determined. This way if the wound size is greater than or equal to three centimeters treatment with triple therapy for 2 weeks will be done and will be followed 4 weeks of treatment with omeprazole. If the wound size is smaller than 2 centimeters treatment with triple therapy for 2 weeks will be done and will be followed 2 weeks of treatment with omeprazole. If RUT test is negative treatment just with omeprazole for 2 weeks is performed. Considering that in the case of ulcers in patients with gastrointestinal bleeding or in the case of PPI or antibiotic use in the last 2 weeks RUT answer may be false negative so in these cases gG H.PYLORI AB-I will be checked. If RUT is positive they will be treated as RUT positive and if RUT is negative they will be treated as RUT negative. Those who are in the intervention group in addition to triple therapy, zinc sulfate 220 mg capsules (Alhavi pharmaceutical company) will be given daily. And the people who are in the control group zinc sulfate 220 mg capsules will not be given.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kurdistan University of Medical Sciences
Street address
Pasdaran St., Kurdistan University of Medical Sciences
City
Sanandaj
Postal code
Approval date
2014-03-05, 1392/12/14
Ethics committee reference number
14/47259

Health conditions studied

1

Description of health condition studied
Peptic ulcer
ICD-10 code
K27
ICD-10 code description
Peptic ulcer, site unspecified

Primary outcomes

1

Description
Ulcer size
Timepoint
6 weeks after initial endoscopy
Method of measurement
The ulcer would be determined by sub-specialist of gastroenterology via endoscopy

Secondary outcomes

1

Description
Complications
Timepoint
During the study and 8 weeks after the initial endoscopy
Method of measurement
Observation and examination by Subspecialist of Gastroenterology

2

Description
Ulcer place
Timepoint
During the initial endoscopy
Method of measurement
Based on the location of ulcer was determined by

gastroenterologist via endoscopy: stomach, antrum, fundus, cardia and duodenum.

3

Description
Diarrhea and vomiting
Timepoint
During the study
Method of measurement
Observation and examination by specialist

4

Description
Dizziness
Timepoint
During the study
Method of measurement
Observation and examination by specialist

Intervention groups

1

Description
In addition to triple therapy, Zinc sulfate 220 mg capsules (Alhavi pharmaceutical company) will be given to people who are in the intervention group daily.
Category
Treatment - Drugs

2

Description
The control group received placebo capsules in addition to triple therapy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tohid Hospital
Full name of responsible person
Morteza Nayebi
Street address
Basij Sq., Geryashan St.,Tohid Hospital
City
Sanandaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Kurdistan University of Medical Sciences
Full name of responsible person
Fardin Gharibi
Street address
Pasdaran St., Kurdistan University of Medical Sciences
City
Sanandaj
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, Kurdistan 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
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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