

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of vitamin A injection on healing of anastomosis in patients with gastrointestinal cancer

Protocol summary

Study aim

Effect of vitamin A injection on healing of anastomosis in patients with gastrointestinal cancer

Design

Factorial Clinical Trial Triple blind , Randomized, Sample Size: 140 (70 persons in each group), Trial Phase: 3, How to Randomize by Using Randomization Lists Set by a biostatistician .

Settings and conduct

In this randomized, Triple blind clinical trial, 140 patients with gastrointestinal cancers (gastric, colon and rectal cancers) undergoing gastrointestinal surgery and anastomosis at Dr. Rahnemoon and Shahid Sadoughi hospitals. Will be selected. Eligible patients will be randomly divided into intervention and control groups (The first group received 50000 international units of vitamin A injection , daily for 3 days after surgery and the second group received placebo). Randomization Lists, will be used to randomly assign the two groups to the intervention and control groups, according to the priority of their surgical history. The clinical symptoms of patients in both groups will be monitored by a specialist physician up to 5 days after surgery, including fever, biliary secretion, leukocytosis, peritonitis, and the need for reoperation. In this study, participants, as well as the researcher, outcome assessor, and data analyst, will be blinded .

Participants/Inclusion and exclusion criteria

Inclusion criteria : People with one of the types of gastrointestinal cancers, including gastric, colon and rectum that undergo gastrointestinal surgery and anastomosis. Exclusion criteria : Malnutrition , History of Alcohol Use , History of corticosteroids Use , Multiple blood transfusions In operation , Emergency surgery , Surgery following recurrence the disease

Intervention groups

Intervention group: Intramuscular injection of 50,000 international units of Vitamin A Control group: Intramuscular injection of 1ml injectable sterile normal

saline

Main outcome variables

Anastomosis Leakage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191127045520N1**

Registration date: **2020-02-04, 1398/11/15**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-04, 1398/11/15**

Update count: **0**

Registration date

2020-02-04, 1398/11/15

Registrant information

Name

sanaz dehghan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3824 1141

Email address

s.dehghan74@iauyazd.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of vitamin A injection on healing of anastomosis in patients with gastrointestinal cancer

Public title
Effect of vitamin A injection on healing of anastomosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
People with one of the types of gastrointestinal cancers, including gastric, colon and rectum that undergo gastrointestinal surgery and anastomosis.
Exclusion criteria:
Malnutrition History of Alcohol Use History of corticosteroids Use Multiple blood transfusions In operation Emergency surgery Surgery following recurrence the disease

Age
To **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
Persons who will be admitted to the treatment centers that qualify for inclusion will be given priority by the date of surgery of these patients, using a Randomization Lists, set by the Biostatistician, Code A or B, and They will be randomly divided into intervention and control groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Vitamin A ampoules or injectable sterile normal saline will be administered by a qualified surgical resident in accordance with the Randomization Lists set by the biostatistician. The resident will not be a researcher, outcome assessor, or data analyst in the study. Nurse who dose not participate in the study will inject vitamin A ampoules or normal saline, so that the vitamin A ampoule or normal saline will be drawn into the syringe before presenting to the patient's bedside and will be injected intramuscularly by the said nurse . Therefore, participants, as well as the researcher, outcome assessor, and data analyst, will be blinded by the lack of knowledge of vitamin A or placebo injections.

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University of Yazd

Street address

Unknown Martyrs Boulevard, Safaieh, Yazd

City

Yazd

Province

Yazd

Postal code

8915813135

Approval date

2019-04-14, 1398/01/25

Ethics committee reference number

IR.IAU.YAZD.REC.1398.001

Health conditions studied

1

Description of health condition studied

Anastomosis leakage in gastrointestinal cancer

ICD-10 code

Z98.0

ICD-10 code description

Intestinal bypass and anastomosis status

Primary outcomes

1

Description

Anastomosis Leakage

Timepoint

5 days after surgery

Method of measurement

Clinical signs including fever, biliary secretion, leukocytosis , Peritonitis and the need for reoperation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intramuscular injection of vitamin A at a dose of 50000 international units (One milliliter) ,

daily, for 3 days after surgery

Category

Treatment - Drugs

2**Description**

Control group: Intramuscular injection of 1ml injectable sterile normal saline , daily , for 3 days after surgery

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Dr.Rahnemoon Hospital

Full name of responsible person

Dr. Jamal Jafari nedooshan

Street address

Shahid Dr. Rahnemoon Hospital , Farrokhi Stree, Yazd

City

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8913814396

Phone

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jamalnedooshan@yahoo.com

2**Recruitment center****Name of recruitment center**

Shahid Sadoughi Hospital

Full name of responsible person

Dr. Saeed Kargar

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Shahid Sadoughi Hospital , Ibn Sina Street, Shahid Ghandi Boulevard, Yazd

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Saeedkargar@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University of Yazd

Full name of responsible person

Dr. Seyed Mohammad Reza Mortazavi Zadeh

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Ali Ibn Abi Taleb School of Medicine, Safaieh,Shohada -e Gomnam Boulevard

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

Yes

Title of funding source

Islamic Azad University of Yazd

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**

Yazd University of Medical Sciences

Full name of responsible person

Haniyeh Dehghan Chenari

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Jamal Jafari nedooshan

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Oncosurgery Fellowship

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Person responsible for updating data

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Position

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Latest degree

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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