

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Investigating the rate of surgical site infection in two methods of continuous and discrete sutures for primary wound closure in gastric and intestinal surgeries: A randomized clinical trial study

Protocol summary

Study aim

Comparison of the rate of surgical site infection in two simple and continuous suture methods for primary wound closure in stomach and intestinal surgeries

Design

Clinical trial, with parallel groups, randomized, on 154 patients. The block randomization method was used for randomization.

Settings and conduct

This study is a randomized clinical trial, which was performed on 154 patients who were referred to the independent educational and medical centers of Qazvin province in 1402, who are candidates for stomach and intestinal surgery according to the surgeon's orders, randomly one of the two methods of suturing (simple and continuous) is done with three-zero nylon thread

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate patients for stomach and intestinal surgery; Age range 18-80 Non-inclusion criteria: Having diabetes; Immune system diseases; History of gastrointestinal surgery; Pregnancy; Drug abuse; Smoking; Intestinal-to-skin fistula; Anastomosis leakage; Peritonitis during surgery; Abscess and collection during surgery; Hypoproteinemia

Intervention groups

One of the two methods of suturing (simple and continuous) with three-zero nylon thread is performed on the patients randomly. The length of the wound and other characteristics are recorded in the checklist. After surgery, patients are hospitalized for seven days.

Main outcome variables

Scar rate, pain, fever, leukocytosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230826059259N1**

Registration date: **2023-08-28, 1402/06/06**

Registration timing: **prospective**

Last update: **2023-08-28, 1402/06/06**

Update count: **0**

Registration date

2023-08-28, 1402/06/06

Registrant information

Name

Sara Arsham

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3379 0620

Email address

sara_arsham@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-06, 1402/06/15

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the rate of surgical site infection in two methods of continuous and discrete sutures for primary

wound closure in gastric and intestinal surgeries: A randomized clinical trial study

Public title

Investigating the rate of surgical site infection in two methods of continuous and discrete sutures for primary wound closure in gastric and intestinal surgeries at the independent educational-therapeutic center Velayat in Qazvin: A randomized clinical trial study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing gastric and intestinal surgery Age range 18-80

Exclusion criteria:

Having diabetes Immune system diseases History of gastrointestinal surgery Pregnancy Smoking, drugs and alcohol Hypoproteinemia

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **154**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of random allocation in this study is Balanced Block Randomization. 6 blocks AABB- ABAB_ ABBA- BBAA- BABA_ BAAB are numbered based on 1 to 6 and numbers 1 to 6 are selected from the table of random numbers and placed together. Then they are replaced with numbered blocks

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 Qazvin University of Medical Sciences

Street address

Research and Technology deputy, 1st Branch, Maudet Alley, Shahid Beheshti Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

3415613911

Approval date

2023-07-30, 1402/05/08

Ethics committee reference number

IR.QUMS.REC.1402.127

Health conditions studied

1

Description of health condition studied

Infection at the surgical suture site

ICD-10 code

T81.4

ICD-10 code description

Infection following a procedure

Primary outcomes

1

Description

Accumulation of pus under the skin

Timepoint

From the time of completion of surgery to thirty days after that

Method of measurement

Clinical examination by a doctor

2

Description

Active secretions from the wound surface

Timepoint

From the time of completion of surgery to thirty days after that

Method of measurement

Clinical examination by a doctor

3

Description

Leukocytosis (white blood cells less than 4500)

Timepoint

From the time of completion of surgery to seven days after that

Method of measurement

CBC test

4

Description

Pain at the wound site

Timepoint

From the time of completion of surgery to thirty days after that

Method of measurement

McGill pain questionnaire

5

Description

Fever

Timepoint

From the time of completion of surgery to thirty days after that

Method of measurement

Clinical examination by a doctor

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Making interrupted suture with three-zero nylon

Category

Treatment - Surgery

2

Description

Intervention group: Making continuous suture with three-zero nylon

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat hospital

Full name of responsible person

Sara Arsham

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22 Bahman Blvd, Tavon Square, Elahiye Quay, Minodar Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyed Mahidi Mirhashemi

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researchdpt@qums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Sara Arsham

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after individuals are de-identified

When the data will become available and for how long

Access starts 6 months after results are published

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any kind of analysis of the delivered data is allowed

From where data/document is obtainable

Refer to Dr. Sara Arsham's email
"sara_arsham@yahoo.com"

What processes are involved for a request to access data/document

After publishing the article, the applicant can send a clear request to the author to access the data by sending an email. So, after reviewing the request within 2 weeks, access to data and information is allowed.

Comments