Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of post-surgical infection frequency, mean length of hospital stay, and surgical outcomes between primary and delayed primary stump closure in diabetic patients undergoing below-knee amputation for diabetic foot

Protocol summary

Study aim

To compare frequency of post-surgical infection, mean hospital stay and surgical outcomes following below knee amputation in diabetics using primary closure versus delayed primary closure

Design

Single-centre, randomized, parallel-group interventional trial of 220 diabetic patients undergoing below-knee amputation, with blinded outcome assessment.

Settings and conduct

The study will be conducted at Combined Military Hospital, Rawalpindi, Pakistan. Adult diabetic patients requiring below-knee amputation will be randomized to primary or delayed primary stump closure groups. Outcomes will be assessed by blinded investigators.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diabetic patients aged 18–75 years being on antidiabetic treatment undergoing below-knee amputation for a single non-salvageable infected limb. Exclusion criteria: advanced cardiac or respiratory disease, planned guillotine amputation, inadequate skin cover for stump formation, loss to follow-up, or refusal to participate.

Intervention groups

Intervention group 1: Primary stump closure. Patients with immediate closure of the stump at the time of surgery. Intervention group 2: Delayed primary closure.Stump closure is performed 72 hours after surgery and managed with wound wash and dressings.

Main outcome variables

Frequency of surgical site infection (SSI); mean hospital stay after procedure; need for re-admission after infection; revision of the procedure; 28-day mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260612069759N1**
Registration date: **2026-07-12, 1405/04/21**
Registration timing: **retrospective**

Last update: **2026-07-12, 1405/04/21**
Update count: **0**

Registration date

2026-07-12, 1405/04/21

Registrant information

Name
Abdul Wahid
Name of organization / entity
Combined Military Hospital Rawalpindi Pakistan
Country
Pakistan
Phone
+92 332 9851374
Email address
wahidmalik973@outlook.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-01, 1403/10/12

Expected recruitment end date

2025-06-30, 1404/04/09

Actual recruitment start date

2025-01-01, 1403/10/12

Actual recruitment end date

2025-06-30, 1404/04/09

Trial completion date
2025-06-30, 1404/04/09

Scientific title
Comparison of post-surgical infection frequency, mean length of hospital stay, and surgical outcomes between primary and delayed primary stump closure in diabetic patients undergoing below-knee amputation for diabetic foot

Public title
Primary vs delayed closure after below-knee amputation in diabetic foot patients.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All male or female diabetic patients Aged 18-75 years of age on treatment Either oral medication or on insulin Presenting for below knee amputation of a single non-salvageable limb with infection below the level of amputation

Exclusion criteria:
Patients with advanced cardiac or respiratory disease Those planned for a guillotine amputation Patients with inadequate skin cover for stump formation Patients unwilling to be included in the study

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **220**
Actual sample size reached: **220**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients were individually randomized in a 1:1 ratio to either primary closure or delayed primary closure using simple randomization by drawing method. At the time of enrollment, each patient drew a pre-prepared slip indicating allocation to one of the two study groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients were not informed of the specific study hypothesis to minimize expectation bias. Outcome assessments were performed by investigators who were blinded to the treatment allocation. Data analysis was also conducted by blinded investigators to ensure objective interpretation of the study results.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Committee, Institutional Review Board Combined Military Hospital Rawalpindi

Street address
Tamiz-ud-din road, lalkurti, Rawalpindi Cantt

City
Rawalpindi

Postal code
46000

Approval date
2024-12-17, 1403/09/27

Ethics committee reference number
1019

Health conditions studied

1

Description of health condition studied
diabetic foot amputation stump

ICD-10 code
Z86.31

ICD-10 code description
Personal history of diabetic foot ulcer

Primary outcomes

1

Description
Surgical Site infection

Timepoint
Postoperative day 7 and 28.

Method of measurement
Clinical wound assessment for pus discharge, foul smell or any signs of infection.

2

Description
Length of hospital stay

Timepoint
At time of discharge from hospital

Method of measurement
Total number of days from surgery to discharge from hospital will be counted

3

Description

Need for readmission after infection.

Timepoint

Within 28 days after surgery

Method of measurement

Follow up visits for infection related readmission and hospital admission record.

4

Description

Revision of the procedure

Timepoint

Within 28 days after surgery

Method of measurement

Below knee amputation stump assessment for requirement of additional surgery

5

Description

28 days mortality

Timepoint

Within 28 days after surgery

Method of measurement

Hospital records and follow-up information

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1:Primary stump closure. Patients undergoing below-knee amputation with immediate closure of the stump at the time of surgery.

Category

Treatment - Surgery

2

Description

Intervention group 2:Delayed primary stump closure. Patients undergoing below-knee amputation in whom stump closure is performed 72 hours after the initial surgery following wound assessment, wound washing, and antiseptic dressing.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Combined military Hospital,Rawalpindi

Full name of responsible person

Abdul Wahid

Street address

Tamiz-ud-din road,Lalkurti,Rawalpindi Cantt

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Phone

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Wahidmalik973@outlook.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Combined Military Hospital, rawalpindi

Full name of responsible person

Abdul wahid

Street address

Tamiz -ud-din road, lalkurti, Rawalpindi cantt

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Phone

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Grant name

Self

Grant code / Reference number

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

No

Title of funding source

Self

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Combined Military Hospital, Rawalpindi

Full name of responsible person

Abdul Wahid

Position

Resident Surgeon

Latest degree

Bachelor

Other areas of specialty/work

General Surgery

Street address

House number 142, K-1 block, WAPDA Town, Lahore, Punjab, Pakistan

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Lahore

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Person responsible for scientific inquiries

Contact

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Combined Military Hospital Rawalpindi ,Pakistan

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
De-identified participant data, study protocol, statistical analysis plan, and final clinical study report related to primary versus delayed primary stump closure in below-knee amputation for diabetic foot will be made available after publication.

When the data will become available and for how long
After Publication of article

To whom data/document is available
medical students and people working in medical institutions

Under which criteria data/document could be used
only for educational purposes not for commercial purposes after publication and approval from primary author

From where data/document is obtainable
Data can be obtained from google drive after sending request to email Wahidmalik973@outlook.com. link for Google drive will be shared to get the data access.

What processes are involved for a request to access data/document
an email will be required and approval will be given by primary author for using the data

Comments