

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Vancomycin as antibiotic lock technique in prevention of catheter associated infection in stem cell transplantation patients

Protocol summary

Study aim

Antibiotic lock therapy(ALT) for the prevention and treatment of catheter-related blood stream infection is a simple strategy for Sterilizing the catheter lumen, involves instilling high concentrations of antibiotics into catheter lumen for extended periods of time. This trial will evaluate the efficacy of Vancomycin lock solution in reducing catheter-related bloodstream infection(CRBSI) among patients underwent hematopoietic stem cell transplantation(HSCT). These patients underwent non-tunneled CVC(ARROW) will be inserted through internal jugular vein newly.

Design

This study will be randomized prospective single blind as case-control group. 60 patients will be assigned to either antibiotic or control group. The case group will be prescribed Vancomycin- heparin lock solution as a catheter lock solution. This solution will be a mixture of 5 mg/ml Vancomycin and 2500 U/ml unfractionated heparin.

Settings and conduct

Antibiotic lock will be continued for total of 21 days from newly insertion. 60 patients who underwent HSCT between February 2019 and January 2020 in Talegani Hospital affiliated to Shaheed Beheshti University will be included in this study. Patients randomly received either heparin only(control group) or a mixture of 5 mg/ml Vancomycin and 2500 U/ml heparin(case group) as catheter lock solution.

Participants/Inclusion and exclusion criteria

All patients undergoing hematopoietic stem cell transplantation who will be inserted CVC newly, include. Exclusion criteria: hypersensitivity to vancomycin

Intervention groups

The Vancomycin (5 mg/ml)- heparin(2500 U/ml) will be considered for case group and heparin only will be administered for control group.

Main outcome variables

Catheter Related Blood Stream Infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003210N18**

Registration date: **2019-09-09, 1398/06/18**

Registration timing: **prospective**

Last update: **2019-09-09, 1398/06/18**

Update count: **0**

Registration date

2019-09-09, 1398/06/18

Registrant information

Name

Maria Tavakoli Ardakani

Name of organization / entity

Faculty of pharmacy, Shaheed Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 3704

Email address

mariatavakoli@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Vancomycin as antibiotic lock technique in prevention of catheter associated infection in stem cell transplantation patients

Public title

Effect of Vancomycin as antibiotic lock technique in prevention of catheter associated infection in stem cell transplantation patientsV

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All of patients undergoing HSCT whom non-tunneled CVC (arrow) will be inserted newly.

Exclusion criteria:

Hypersensitivity to Vancomycin

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Block Randomization The randomization scheme consists of a sequence of blocks such that each block contains 10 number of intervention assignments in random order. The BMT ward of Taleghani Hospital consisted of two nursing station (S1 and S2). In one station (S1), heparin plus vancomycin lock will be performed and in the other station, heparin lock will be done on patients. Equal allocation will be planned in a two-armed trial (S1 and S2) using a randomization scheme of permuted blocks. Investigator plans to enroll 10 subjects per month. Individuals in this group were randomly assigned to one the two aforementioned nursing stations. Randomization will be done to generate random sequences on the web (http://www.graphpad.com/quick_calc/index.cfm). Each patient will go to one of the station based on randomization sequence. Block will be done for 21 days from catheterization day. Allocation concealment randomization will done from a SNOSE method, and will be kept by the hospital pharamcist of the two stations.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will be unaware of their allocated group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Department of Clinical Pharmacy, School of Pharmacy
Shahid Beheshti University of Medical Sciences
Tehran, IRAN

City

Tehran

Province

Tehran

Postal code

14155-6153

Approval date

2019-02-19, 1397/11/30

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.1361

Health conditions studied

1

Description of health condition studied

catheter- related Blood stream infection (CRBSI)

ICD-10 code

B95

ICD-10 code description

Streptococcus, Staphylococcus, and Enterococcus as the cause of diseases classified elsewhere

Primary outcomes

1

Description

fever, erythema, purulence (catheter exit site), swelling

Timepoint

observe for 21 days from catheterization

Method of measurement

clinical examination, thermometer

2

Description

infection

Timepoint

observe for 21 days from catheterization

Method of measurement

Blood culture (peripheral, catheter)

Secondary outcomes

1

Description

WBC and Platelet engraftment

Timepoint

start of antibiotic lock until 21 days after

Method of measurement

CBC

2

Description

Hospitalization time

Timepoint

from day of antibiotic lock until hospital clearance

Method of measurement

Day count

Intervention groups

1

Description

Intervention group (5 mg vancomycin, 2500 IU/ml heparin): Every night at a certain time, patients in the intervention group receive the block solution (vancomycin-heparin). This block is done for each patient in a 21- day time interval from the day of catheterization. The block time is at least 8 hours but depending on catheter availability it may increase. When dwell time is over, researcher aspirates antibiotic lock solution from catheter lumen, flush catheter with 5ml normal saline before using line to administer medication. This process is done by the trained nurse. Lock solution is prepared based on its stability every 72 hour by pharmacist. Solution vancomycin-heparin stable 72 hours in room temperature based on Antibiotic Lock solution Therapy Guideline.

Category

Treatment - Drugs

2

Description

Control group (Heparin only 100IU/ml base on routine program in ward): This block is done for each patient in a 21-day time range started at the day of catheterization. The block time will be at least 8 hours and depending on availability catheter may increase

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

The bone marrow transplantation Department of Taleghani hospital

Full name of responsible person

Maria Tavakoli Ardakani

Street address

Department of Clinical Pharmacy School of Pharmacy
Shahid Beheshti University of Medical Sciences
Tehran, Iran

City

Teharan

Province

Tehran

Postal code

14155-6153

Phone

+98 21 8820 0085

Fax

+98 21 8887 3704

Email

mariatavakoli@sbm.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maria Tavakoli Ardakani

Street address

Department of clinical Pharmacy School of Pharmacy

City

Tehran

Province

Tehran

Postal code

14155-6153

Phone

+98 21 8820 0085

Fax

+98 21 8887 3704

Email

mariatavakoli@sbm.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

50

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maria Tavakoli Ardakani

Position

Assistant Professor in Clinical Pharmacy, School of Pharmacy, Shahid Beheshti University of Medical

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Department of Clinical Pharmacy School of Pharmacy
Shahid Beheshti University of Medical of Sciences
Theran, Iran

City

Tehran

Province

Tehran

Postal code

14155-6153

Phone

+98 21 8820 0085

Fax

+98 21 8887 3704

Email

mariatavakoli@sbm.ac.ir

+98 21 8887 3704

Email

mariatavakoli@sbm.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soodabeh Shahkarami

Position

Pharm D student

Latest degree

Master

Other areas of specialty/work

Medical Pharmacy

Street address

Department of Clinical Pharmacy School of Pharmacy
Shahid Beheshti University of Medical Sciences,
Theran, Iran

City

Tehran

Province

Tehran

Postal code

14155-6153

Phone

+98 21 8820 0085

Fax

+98 21 8887 3704

Email

soodabehshahkarami@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maria Tavkoli Ardakani

Position

Assistant Professor in Clinical Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Shahid Beheshti University of Medical Sciences
Tehran, Iran

City

Tehran

Province

Tehran

Postal code

14155-6153

Phone

+98 21 8820 0085

Fax

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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable