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 Streilizing 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 soultion 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 wil be prescribed Vancomycin- heparin lock solution as a catheter lock solution. This solution will be a mixure 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 Shaid Beheshti University will be included in this study. Patients randomly received either heparin only(control group) or a mixure 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: hypersensitvity 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 Infectin

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
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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:
Hypersensivity 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 wil 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
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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 (vacomycin-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 it's 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
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Sponsors / Funding sources

1

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

Latest degree
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Medical Pharmacy

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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
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