Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A comparison of the effect of taurolidine and 4 % citrate(TauroLock™-HEP500) and Heparin use in Port catheter on the function of catheter and prevention of catheter complications in children with malignancy

Protocol summary

Study aim

A comparison of the effect of taurolidine and ۴ % citrate and Heparin use in Port catheter on the function of catheter and prevention of catheter complications in children with malignancy

Design

Sampling in this study is convenience sampling method. This clinical trial has a control group, with parallel groups, single-blinded, non-randomized, phase 3 on 72 patients.

Settings and conduct

Sampling is collected from patients referred to the Oncology Department of Ali Asghar Hospital in Tehran. All patients have Polysite (Vygon) single lumen catheters . Based on clinical needs, After each treatment cycle, the patient's port catheters are filled with a solution of about 5 cc of heparin varnish in the first group, and in the second group, a solution of 2.5 to 3 cc of Taurolock solution is used.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: 1- Age between 1 month and 19 years 2- The need to have a port catheter for the purposes of chemotherapy for malignancies, not just transfusion of blood and blood products. 3-Informed consent Exclusion criteria: 1- Patients who are transferred to departments other than oncology 2- Patients who have hereditary coagulation disease. 3- Patients who have a non-tunneled Port catheter. 4- Patients who have hematological diseases without neutropenia (such as Diamond Blackfan anemia and sickle cell anemia).

Intervention groups

In the intervention group, which includes 38 patients, after each cycle of chemotherapy, the catheter port is filled with 5 cc of Tauoolock solution. In the control group, which includes 38 patients, after the end of each chemotherapy, after washing the Port Catheter with normal saline, they will be varnished with a sufficient amount of Heparin solution.

Main outcome variables

This study measures the function of the catheter during the 6 months. ; inflammatory markers: including IL-6, Total WBC, CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201107049296N4**
Registration date: **2023-10-22, 1402/07/30**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-22, 1402/07/30**
Update count: **0**

Registration date

2023-10-22, 1402/07/30

Registrant information

Name
Aziz Eghbali
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2024-01-30, 1402/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effect of taurolidine and 4 % citrate(TauroLock™-HEP500) and Heparin use in Port catheter on the function of catheter and prevention of catheter complications in children with malignancy

Public title

Assessment of TauroLock™ in port catheter

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children who have recently been diagnosed with malignancy requiring chemotherapy Children who need Port-a-Cath for treatment of malignancy, not only transfusion. Consent of patients' parents and implicit consent of children with decision-making capacity Children Aged between 1 month to 19 years

Exclusion criteria:

Having congenital coagulation disorder Having non-tunneled Port-a-Cath History of congenital hematologic disorders

Age

From **1 month** old to **19 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

For this study, we will use the stratified block randomization method to allocate patients into two groups, A and B, with a 1:1 ratio. The blocks will be of sizes 6 and 8 and will be stratified according to age. The age groups are 0-5 years, 5-9 years, 9-14 years, and 14-18 years. We will use www.sealedenvelope.com to provide the randomization. The information will be entered into the website in groups A and B, with a list length appropriate for the sample size and the previously mentioned stratification. The main researcher will receive the results once the allocation is complete.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, blinding was done only for the outcome assessor, the third collaborator of the project who reviews the patients' tests and clinical data without knowing the patient's allocation to a specific group. The Methodologist also analyses the data generally without knowing whether each data belongs to a specific group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran university of medical science., Next to Milad Tower., Hemmat Highway., Tehran

City

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Province

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Postal code

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Approval date

2023-10-07, 1402/07/15

Ethics committee reference number

IR.IUMS.REC.1402.598

Health conditions studied

1

Description of health condition studied

Drugs used in chemotherapy

ICD-10 code

Z51.1

ICD-10 code description

Chemotherapy session for neoplasm

Primary outcomes

1

Description

Serum Interleukin-6 level

Timepoint

Before intervention, 1 month after entering the study and 6 month after entring

Method of measurement

Patients' serologic examinations; the serum IL-6 level will be measured in pg/dl

2

Description

Duration of Port-a-Cath function

Timepoint

On the first medical contact and then every chemotherapy session or every month (whichever is earlier) up to 6 months.

Method of measurement

The number of days that the port catheter has had a diagnostic or therapeutic function so that blood and fluids can move in both directions.

Secondary outcomes

1

Description

Serum CRP level

Timepoint

At the beginning of the study the 1 month later and 6 months later

Method of measurement

Serum CRP level will be measured by serologic examinations.

Intervention groups

1

Description

Intervention group: All patients have a single-lumen Polysite(Vygon) catheter. Catheters are used for the purposes of chemotherapy and the transfer of blood and serum products and other drugs. A bio-occlusive adhesive is also placed at the exit of the catheter from the skin, which is changed every three days, and the area will be disinfected with a Povidone-iodine solution. Based on the patient's clinical needs, port catheters are used after each treatment cycle in the intervention group from 2.5 to 3 cc of Taurolock™ solution (Taurolidine 1.35%/sodium cirate 4% Taurolock™, Tauropharm, Waldbuttelburn, Germany).

Category

Treatment - Drugs

2

Description

Control group: In the control group, all patients have single-lumen Polysite (Vygon) catheters. The catheters are used after being placed subcutaneously by a pediatric surgeon under standard and identical conditions for the purposes of chemotherapy and the transfer of blood and serum products and other drugs. According to the patient's clinical needs, the port catheters are diluted with 5 cc of heparin lock solution (5000 IU heparin/0.2 ml) Darou Pakhsh, Tehran, Iran, diluted up to 100 IU heparin/ml with 0.9% sterile normal saline after each treatment cycle

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Ali Asghar Children's Hospital

Full name of responsible person

Aziz Eghbali

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Ali Asghar Children's Hospital, Zafar St, Modares Hwy

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran 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
Iran University of Medical Sciences

Full name of responsible person
Aziz Egbali

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Hematology

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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