

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparative clinical study of the effectiveness of TauroLock™ solution with piperacillin-tazobactam as secondary prophylaxis of Port-Catheter infection in children with cancer

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Comparison the effectiveness of TauroLock™ solution with piperacillin-tazobactam as secondary prophylaxis of Port-a-Cath infection in children with cancer.

Design

This is a double-blind, randomized, controlled clinical trial in which a random block method is used and two groups are in parallel.

Settings and conduct

Amir Oncology Hospital. In this study, the participants and the evaluator (the microbiologist who records the final result of the growth medium) will be unaware of the intervention groups.

Participants/Inclusion and exclusion criteria

Patients between 0-19 years old who suffer from cancer and have the port in Amir Oncology Hospital Exclusion criteria: critically ill patients, patients who have an active fungal infection and give antifungal treatments.

Intervention groups

Intervention group: 3-5 milliliters of piperacillin-tazobactam from 10 micromoles/ml will be injected into port when the port is not in use. This dose will be repeated every 14 days. Control group: 3-5 milliliters of TauroLock HEP 100 antiseptic solution will be injected into port when the port is not in use. This dose will be repeated every 14 days.

Main outcome variables

The incidence of bloodstream infection due to port infection

Last update: **2018-06-08, 1397/03/18**

Update count: **0**

Registration date

2018-06-08, 1397/03/18

Registrant information

Name

Nazafarin Hatami mazinani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3627 0861

Email address

stud0310548225@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative clinical study of the effectiveness of TauroLock™ solution with piperacillin-tazobactam as secondary prophylaxis of Port-Catheter infection in children with cancer

Public title

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180309039013N1**

Registration date: **2018-06-08, 1397/03/18**

Evaluation of the effect of TauroLock™ and piperacillin-tazobactam in secondary prophylaxis of Port-Catheter infection.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Having Port-Catheter Age between 0-19 Having cancer

Exclusion criteria:

Critically ill patients Patients with severe coagulation problems No permission from child's parents

Age

From **1 day** old to **19 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method was used which the patient was the randomization unit. For this purpose, computer software was used to define the blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the participants and the evaluator (the microbiologist who records the final result of the growth medium) will be unaware of the intervention groups. For blinding the statistical specialist, the encoding of the groups and participants will be done by a third person and the code definition will not be available to the statistician. additionally, due to the nature of the study, physician and the nurses will be aware of the control and intervention groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, setad Ave., Zand Blvd., Shiraz

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2016-11-14, 1395/08/24

Ethics committee reference number

IR.SUMS.MED.REC.1395.45

Health conditions studied

1

Description of health condition studied

Infection due to port catheter

ICD-10 code

T85.7

ICD-10 code description

Infection and inflammatory reaction due to other internal prosthetic devices, implants and grafts

Primary outcomes

1

Description

The rate of infection of systemic bloodstream incidence due to port infection

Timepoint

Before the beginning of the intervention, once a day during the intervention, and at the end of the intervention

Method of measurement

Positive blood culture according to standard microbiological process

Secondary outcomes

1

Description

Port survival rate (No need to exit port or reload)

Timepoint

Once a day during the intervention, and at the end of the intervention

Method of measurement

I will record the change of port by observation.

Intervention groups

1

Description

Intervention group: Individuals in this group will be injected from the antibiotic solution of Piperacillin Tazobactam in proportion to the port volume, 3-5 cc.

Category

Prevention

2

Description

Control group: Individuals in this group will be injected from the TauroLock™ solution in proportion to the port volume, 3-5 cc.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir oncology hospital

Full name of responsible person

Nazafarin Hatami Mazinani

Street address

Amir Oncology Hospital, Station 11 of Farhangshahr, Shiraz

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+98 71 3632 3731

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seied Basir Hashemi

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Ali Amanati

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Ali Amanati

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Nazafarin Hatami mazinani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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

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