

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Catheter related bacterial infections in convenient versus needle-less (Planecta®) intravenous infusion systems in Mofid Children Hospital pediatric-ICU

Protocol summary

Summary

Intravenous catheter related infections are from critical infections in hospitals especially in pediatric-ICUs. Several benefits in addition to preventing intravenous catheter related infections are mentioned for Planecta® closed injection system (JMS Co., Ltd.). The aim of this study is to compare the frequency of intravenous catheter related infections in P-ICU patients admitted to Mofid Hospital (Tehran, Iran) using Planecta® or conventional injection systems. Inclusion/exclusion criteria are: age range of one month to 14 years, at least 24 hours staying in P-ICU. Patients will be randomly allocated to the interventions according to the beds which will be assigned to each intervention every other one. Primary outcome is any intravenous catheter related infection e.g. phlebitis and septicemia that will be diagnosed according to the scientific definitions run in the ward.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138805122287N1**
Registration date: **2009-09-26, 1388/07/04**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-09-26, 1388/07/04

Registrant information

Name

Ahmad Reza Shamshiri

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Representative of JMS co, in Iran

Expected recruitment start date

2007-01-21, 1385/11/01

Expected recruitment end date

2007-10-22, 1386/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Catheter related bacterial infections in convenient versus needle-less (Planecta®) intravenous infusion systems in Mofid Children Hospital pediatric-ICU

Public title

Catheter related bacterial infections in convenient versus needle-less (Planecta®) intravenous infusion systems in Mofid Children Hospital pediatric-ICU

Purpose

Prevention

Inclusion/Exclusion criteria

Age range of 1 month to 14 years, no limitation for gender, no limitation for underlying disease or cause of admission, at least 24 hours staying in p-ICU

Age

To **14 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample sizeTarget sample size: **254****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee in Medical Research - Shahid Beheshti Medical University

Street address

Evin Ave, Shahid Beheshti Medical University

City

Tehran

Postal code**Approval date**

2007-12-15, 1386/09/24

Ethics committee reference number

8448 / 3 / 10 / 25 / پ

Health conditions studied**1****Description of health condition studied**

Intravenous catheter related infections

ICD-10 code

T82.7

ICD-10 code description

Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts

Primary outcomes**1****Description**

Intravenous catheter related infection

Timepoint

During admission to discharge from the ward

Method of measurement

Superficial infections diagnosed with any sign of local infection including pain, local tenderness, warmth and fever without other causes that relieve after 24-48hrs of catheter removal. Blood stream infections diagnosed according to the National Nosocomial Infections Surveillance System (NNISS) with blood sampling after 48hrs of admission.

Secondary outcomes**1****Description**

Duration of stay in the ward

Timepoint

At discharge

Method of measurement

Duration between admission to discharge (or death)

2**Description**

Mortality due to any cause

Timepoint

At discharge

Method of measurement

By checking vital signs

Intervention groups**1****Description**

Intervention group: Planecta infusion system including Planecta vial, Planecta spike, Planecta adaptor, Planecta port, Planecta triple port and Extension tube; In our study infusion systems will be introduced on admission until discharge from the ward. Their setting-up and intervals for changing the devices will be done according to the manufacturers' advices.

Category

Treatment - Devices

2**Description**

Control group: Routine Iranian infusion systems such as SUPA, including spike, adaptor, port, triple port and Extension tube; In our study infusion systems will be introduced on admission until discharge from the ward. Their setting-up and intervals for changing the devices will be done according to the manufacturers' advices.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center**

Name of recruitment center

Pediatric infection research center Shahid Beheshti
Medical University - Mofid Hosp. (Tehran)

Full name of responsible person

Dr Abdollah Karimi

Street address

Mofid Children Hosp., next to the Hoseinie-Ershad,
Shariati Ave.

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Teda Co.

Full name of responsible person

Seyed Hossein Lesan

Street address

Teda building, No. 11.1, Niroo st, Shariati Ave.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Teda Co.

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Pediatric infection research center Shahid Beheshti
Medical University

Full name of responsible person

Saeed Maham

Position

Physician

Other areas of specialty/work**Street address**

Shariati Ave, Mofid Hosp.

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Pediatric infection research center Shahid Beheshti
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Full name of responsible person

Alireza Fahimzad

Position

Pediatric infectious dis. subspecialist

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Web page address**Person responsible for updating data****Contact****Name of organization / entity****Full name of responsible person**

Ahmad Reza Shamshiri

Position**Other areas of specialty/work****Street address****City****Postal code****Phone****Fax****Email**

ar_shamshiri@yahoo.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty