

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of improving the performance of central venous catheter care in the intensive care unit

Protocol summary

Study aim

Reduction of catheter associated infections

Design

A clinical trial with a control group, with two parallel arms, one-way blind, randomized, and phase 2 on 60 patients. A sealed envelope will be used for randomization.

Settings and conduct

The study will be conducted as a clinical trial at 3-month intervals in the General Intensive Care Unit and Brain Surgery. The intervention group in the general intensive care unit will be monitored by a checklist prepared for the proper care of the central vein catheter, and the control group in the intensive care unit of the brain surgery will be performed without a checklist and according to the usual care routine.

Participants/Inclusion and exclusion criteria

CV line for at least 48 hrs admission in the ICU

Intervention groups

Intervention group: 30 patients admitted to the General Intensive Care Unit who will have a central catheter for at least 48 hours and will receive standard care along with routine care. Control group: 30 patients admitted to the intensive care unit of brain surgery who will have a central catheter for at least 48 hours and will receive only routine care.

Main outcome variables

Redness around the catheter Pus and discharge from the tunnel and inside the catheter

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211109053016N1**

Registration date: **2022-05-19, 1401/02/29**

Registration timing: **retrospective**

Last update: **2022-05-19, 1401/02/29**

Update count: **0**

Registration date

2022-05-19, 1401/02/29

Registrant information

Name

Behrouz Naghili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 5411

Email address

naghili_b@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of improving the performance of central venous catheter care in the intensive care unit

Public title

The effect of improving the performance of central venous catheter care

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

CV line for at least 48 hrs Admission in the ICU People over 14 years old Completion of written informed consent form by the patient or companions in case of unconsciousness

Exclusion criteria:

Having neurological disorders (stroke-Parkinson's disease) and known psychological diseases based on patient statement and medical record Having chronic uncontrollable diseases (such as advanced diabetes and malignancies)

Age

From **14 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **3**

monitoring of catheter infection at periodic visit

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

First, patients or patient companions will receive information about the research and study groups, as well as how the groups are cared for. They will then be randomly assigned to one of the study groups using a sealed envelope. But they will not know which care is used or in which group.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Daneshgah St. Emamreza Hospital - Infectious Diseases Department

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Approval date

2021-09-13, 1400/06/22

Ethics committee reference number

IR.TBZMED.REC.1400.576

Health conditions studied

1

Description of health condition studied

Control of nosocomial infections

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Reduction of catheter associated infection

Timepoint

Catheter-associated infections will be compared at the initiation of the project and at the end

Method of measurement

Infection cases will recorded by personnel with checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 patients admitted to the general intensive care unit who will have a central catheter for at least 48 hours and will receive standard care along with routine care.

Category

Treatment - Other

2

Description

Control group: 30 patients admitted to the intensive care unit of brain surgery who will have a central catheter for at least 48 hours and will receive only routine care.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emamreza hospital

Full name of responsible person

Behrouz Naghili

Street address

Daneshghah St. Emamreza Hospital - Infectious
Diseases Department

City

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Postal code

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Phone

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Email

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Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Shahabi

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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

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Behrouz Naghli

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

Tabriz University of Medical Sciences

Full name of responsible person

Behrouz Naghili

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Zahra Abbasi

Position

Infection control nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

En In adress: RDCC.tbzmed.ac.ir

When the data will become available and for how long

Every time

To whom data/document is available

Every one

Under which criteria data/document could be used

Modeling of the subject and method is allowed

From where data/document is obtainable

Send an email to naghili_b@yahoo.com or visit
RDCC.tbzmed.ac.ir.

What processes are involved for a request to access data/document

Send an email to naghili_b@yahoo.com or visit
RDCC.tbzmed.ac.ir.

Comments