

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effect of urinary catheter removal time on the incidence of urinary infection and satisfaction level in patients undergoing lower extremity fracture surgery

Protocol summary

Study aim

The effect of urinary catheter removal time on the incidence of urinary infection and satisfaction level in patients undergoing lower extremity fracture surgery

Design

In this research, 96 patients undergoing lower limb fractures surgery referring to Imam Khomeini Hospital and Bank Melli Iran Hospital will be selected using blocks (9 blocks) and divide into 3 groups.

Settings and conduct

Catheterization will be done in three intervention groups. After leaving the catheter in each group, urine culture and analysis will be performed to examine the urinary tract infection in patients. The study will be done in Imam Khomeini Hospital and Bank Melli Iran Hospital. The study is Double-blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18-60 years; Placement in the lower extremity surgery list Exclusion criteria: urinary tract infection; common chronic diseases (Diabetes, Heart failure, Renal failure, Chronic Obstructive Pulmonary Disease); Multiple Trauma; other infections

Intervention groups

The study has 3 groups: First intervention group: People who their urinary catheter exits 24 hours after catheterisation. Second intervention group: People who their urinary catheter exits 48 hours after catheterisation. Third intervention group: People who their urinary catheter exits 72 hours after catheterisation.

Main outcome variables

The incidence of urinary tract infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180208038670N1**

Registration date: **2018-04-22, 1397/02/02**

Registration timing: **prospective**

Last update: **2018-04-22, 1397/02/02**

Update count: **0**

Registration date

2018-04-22, 1397/02/02

Registrant information

Name

Tahereh Haghparast

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2208 6522

Email address

shirinehaghparast1389@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-29, 1397/02/09

Expected recruitment end date

2018-07-31, 1397/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of urinary catheter removal time on the incidence of urinary infection and satisfaction level in

patients undergoing lower extremity fracture surgery

Public title
The effect of urinary catheter removal time on the incidence of urinary infection

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 60 years Placement in the lower extremity surgery list absence of chronic underlying diseases (Diabetes, Heart failure, Renal failure, Chronic Obstructive Pulmonary Disease) no urinary tract infection prior to catheterization
Exclusion criteria:
urinary tract infection common chronic diseases (Diabetes, Heart failure, Renal failure, Chronic Obstructive Pulmonary Disease) Multiple Trauma other infections

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization with blocks

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding will be done by coding with letters A, B, C for division of the groups. The patient does not know about group method and does not know which group he/sh is located in .

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee on Research in Nursing and Midwifery Faculty and Faculty of Rehabilitation

Street address

Nursing and Midwifery Faculty, East Nusrat Street,

Tohid Square
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2017-12-05, 1396/09/14
Ethics committee reference number
IR.TUMS.FNM.REC.1396.4167

Health conditions studied

1

Description of health condition studied

urinary infection

ICD-10 code

T83.0

ICD-10 code description

Mechanical complication of urinary (indwelling) catheter

Primary outcomes

1

Description

The incidence of urinary tract infection

Timepoint

during catheterization and 72 hours after catheterization.

Method of measurement

Culture and urine analysis

Secondary outcomes

1

Description

Patient satisfaction with urination

Timepoint

72 hours after catheterization, and when the patient experienced at least one voluntarily urination after catheter removal.

Method of measurement

patient satisfaction questionnaire

Intervention groups

1

Description

First intervention group: People who their urinary catheter exits 24 hours after catheterisation.

Category

Prevention

2

Description

Second intervention group: People who their urinary

catheter exits 48 hours after catheterisation.

Category

Prevention

3

Description

Third intervention group: People who their urinary catheter exits 72 hours after catheterisation.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Tahereh Haghparast

Street address

Imam Khomeini Hospital Complex, The end of Keshavarz boulevard, Tehran

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2

Recruitment center

Name of recruitment center

Bank Melli Iran Hospital

Full name of responsible person

Tahereh haghparast

Street address

Bank Melli Iran Hospital, Ferdowsi street, Terhran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Younesian

Street address

Central building of Tehran University of Medical Sciences, Qods Street, Keshavarz Boulevard.

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Grant name

Thesis

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Tahereh Haghparast

Position

Master of Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Name of organization / entity

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Assistant Professor

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Web page address

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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes' data, including testing,
interventions and results of intervention will be shared.

When the data will become available and for how long

Access starts after the publication of the results.

To whom data/document is available

Researchers of academic institutions

Under which criteria data/document could be used

Presenting a Introduction letter from the University

From where data/document is obtainable

E-mail: shirinehaghparast1389@yahoo.com , Tahereh
Haghparast

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

After receiving the request and the introduction letter,
Tehran University of Medical Sciences will get permission
and the file will be sent to them.

Comments