Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Iran (Islamic Republic of)

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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

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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

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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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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