

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Evaluation of the effect of using a special waterproof layer under the tourniquet cuff on the burn incidence and pain intensity after surgery in the patient and the level of satisfaction of operating room staff in knee arthroscopic surgeries

Protocol summary

Study aim

Determining the effect of the use of a special tourniquet on the incidence of burns and the severity of pain after the operation of the patient and the satisfaction level of the operating room personnel

Design

The clinical trial has a control group, with a parallel group, a blind strain of the statistical analyzer, phase 2 on 34 patients. Simple random method

Settings and conduct

This study is conducted in the form of a randomized clinical trial study of a blinded statistical analyst; This means that the statistical analyzer will remain unaware of the division of groups and groups of each patient. The place of research is Isfahan University of Medical Sciences. study groups: Even days: Using a special waterproof drip under the tourniquet cuff: a tourniquet will be used under which a special tourniquet will be used. Odd days: an inflatable tourniquet is used under which four layers of vibril made of 100% cotton are used.

Participants/Inclusion and exclusion criteria

Entry conditions: arthroscopic knee surgery with the need to use a tourniquet. The condition of non-entry: the surgery is an emergency

Intervention groups

Sampling intervention group on even days: using a special waterproof drape under the tourniquet cuff: the tourniquet used is an inflatable type, under which a special tourniquet drape will be used to protect the skin. Odd days sampling control group: using the usual layers under the tourniquet cuff: the tourniquet used is an inflatable tourniquet with four vibril layers made of 100% pure cotton under it. It will be used to protect the skin.

Main outcome variables

Patient's pain after surgery in the place of tourniquet cuff

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220718055487N1**

Registration date: **2022-07-26, 1401/05/04**

Registration timing: **prospective**

Last update: **2022-07-26, 1401/05/04**

Update count: **0**

Registration date

2022-07-26, 1401/05/04

Registrant information

Name

Nafise Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4425 4561

Email address

nafiserahimi7@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-19, 1401/05/28

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Other
Scientific title Evaluation of the effect of using a special waterproof layer under the tourniquet cuff on the burn incidence and pain intensity after surgery in the patient and the level of satisfaction of operating room staff in knee arthroscopic surgeries	Other design features
Public title Evaluation of the effect of using a special waterproof layer under the tourniquet cuff on the burn incidence and pain intensity after surgery	Secondary Ids empty
Purpose Other	Ethics committees
Inclusion/Exclusion criteria Inclusion criteria: Age 18 and over Informed consent to participate in the study Arthroscopic knee surgery with the need to use a tourniquet The surgery is not an emergency Absence of fractures in other body organs based on the information in the patient's file No history of cardiovascular diseases such as congestive heart failure, cardiac arrhythmias, high blood pressure, diabetes based on patient file Non-use of drugs or continuous use of alcohol or cigarettes more than 5 packs per year based on the person's self-report The absence of trauma to the chest, head or abdomen based on the person's self-report No need for other surgeries, in addition to orthopedic surgery, based on the patient's file Absence of coagulation diseases or the need to take anti-coagulation drugs based on the person's medical and medical history Exclusion criteria:	1 Ethics committee Name of ethics committee Ethical Committee of Isfahan University of Medical Sciences - Al-Zahra Research Center Street address No.10, mojang alley, east yeganeh alley, bahar ave, marzadaran blv, tehran City Tehran Province Tehran Postal code 1461844371 Approval date 2022-07-09, 1401/04/18 Ethics committee reference number IR.ARI.MUI.REC.1401.115
Age From 18 years old	Health conditions studied
Gender Both	1 Description of health condition studied Burns of the patient after surgery caused by the use of monopolar cautery - pain after surgery of the patient at the place of closure of the tourniquet
Phase N/A	ICD-10 code ICD-10 code description
Groups that have been masked Data analyser	Primary outcomes
Sample size Target sample size: 34	1 Description Patients who suffer from monopolar cautery burns after surgery Timepoint Before surgery, immediately after surgery Method of measurement Direct observation by the student and completion of the relevant checklist
Randomization (investigator's opinion) Randomized	2 Description Pain after surgery of patients in the place of tourniquet Timepoint Immediately after surgery, up to 24 hours after the patient enters recovery (every 8 hours) Method of measurement Visual analogue scale
Randomization description Randomization method: simple In this study, considering that the distribution of patients will be done by the day of surgery (patients on even and odd days), therefore, there is no tool for randomization.	
Blinding (investigator's opinion) Single blinded	
Blinding description This study is conducted in the form of a randomized clinical trial study of a blinded statistical analyst; This means that the statistical analyzer will remain unaware of the division of groups and groups of each patient.	
Placebo Not used	
Assignment	

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Description

Personnel satisfaction with the waterproof tourniquet cover

Timepoint

Immediately after the intervention

Method of measurement

Satisfaction questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Using a special waterproof drip under the tourniquet cuff (17 people): After preparing the patient and inducing anesthesia, an inflatable tourniquet is used under which a special tourniquet drape will be used to protect the skin.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital, Isfahan

Full name of responsible person

Soheila bakhtiari

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No. 35, tabatabaei alley, kamal esmaeil ave, isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shiva mortazavi

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Research and Technology Vice-Chancellor, building
No 4, Sciences and Health Care Services, Isfahan
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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Nafise rahimi

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Operating room expert

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Person responsible for scientific inquiries

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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

No - There is not a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The report of the results of the personnel satisfaction questionnaire for the use of a special tourniquet and the report of the results of the checklist for burns and pain after surgery in patients.

When the data will become available and for how long

Access starts 6 months after the results are published

To whom data/document is available

Researchers affiliated with universities and scientific institutions

Under which criteria data/document could be used

The results of the data in order to find new solutions to reduce complications caused by the use of tourniquets

From where data/document is obtainable

Nafise Rahimi Telephone Number : 00989059856560
Email: Nafiserahimi7@gmail.com Address: No.10, mojgan alley, east yeganeh alley, bahar ave, marzdaran blv, tehran

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

Email the identification card related to the scientific institute or university to Nafiserahimi7@gmail.com.

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

Esfahan University of Medical Sciences

Full name of responsible person

Nafise rahimi

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

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