

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Evaluation of the effect of digital monitoring system on weight-bearing of patients undergoing orthopedic lower extremities surgery on surgical success

#### Protocol summary

##### Study aim

The aim of this study was to determine the effect of using an intelligent monitoring system with cane or shoe a sensor in comparison with a cane and shoes without a sensor on the success of surgery with patient weight-bearing.

##### Design

This study was a parallel randomized controlled trial study design. The sample size of the study is 216 patients that will be assigned to intervention and control groups using simple randomization method.

##### Settings and conduct

Evaluation of patients' outcomes is in the 1st, 2nd and 3rd months after surgery with radiography. This study will be performed in the orthopedic ward of Rasoul Akram Hospital of Iran University of Medical Sciences. Because the intervention processes are well known in the groups, both the patient and the treating physician are aware of the interventions, so the blind groups in this study were considered final outcome evaluators and data analyzers.

##### Participants/Inclusion and exclusion criteria

The main inclusion criteria are patients with orthopedic surgery of the lower extremities and over 18 years of age, and the non inclusion criteria can be referred to having an infection.

##### Intervention groups

All patients undergoing lower extremities surgery will be used cane and shoes to weigh-bearing. Only in the intervention group will be used shoes and canes with a sensor that records the amount of permissible and impermissible weight-bearing by the patient with the help of a monitoring system.

##### Main outcome variables

Callus formation; Postoperative infection

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220304054177N1**

Registration date: **2022-03-09, 1400/12/18**

Registration timing: **prospective**

Last update: **2022-03-09, 1400/12/18**

Update count: **0**

##### Registration date

2022-03-09, 1400/12/18

##### Registrant information

##### Name

Sahand CheraghilooheSara

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2214 8261

##### Email address

sahand.cheraghi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-03-19, 1400/12/28

##### Expected recruitment end date

2023-03-20, 1401/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of the effect of digital monitoring system on weight-bearing of patients undergoing orthopedic lower extremities surgery on surgical success

## Public title

Evaluation of the effect of digital monitoring system on surgical success

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with joint replacement surgery Patients with fracture surgery Patient willingness to participate in the study

### Exclusion criteria:

Having an infection Unavailability of the patient for follow-up

## Age

From **18 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Outcome assessor
- Data analyser

## Sample size

Target sample size: **216**

## Randomization (investigator's opinion)

Randomized

## Randomization description

After the participants were selected to study, we will use simple randomization method to assign participants to the groups for received intervention and comparison. The randomization process will be performed using Random Allocation software, and since this study consists of two groups, the allocation outputs of the participants will be identified by A and B so the assign of each patient in each group is unpredictable to other members of the research team. We will notify for the team manager after selecting each patient and they will determine the type of group each person according to the software output.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Double blinding was considered for this study. Due to the different process of interventions in the study groups, the patient outcome assessor and data analyzer will be blinded of the type of patient interventions.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Iran University of Medical Sciences

##### Street address

Iran University of Medical Sciences, Shahid Hemmat highway

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۳۹۶۱۴۵۳۵

#### Approval date

2022-02-22, 1400/12/03

#### Ethics committee reference number

IR.IUMS.REC.1400.1117

## Health conditions studied

### 1

#### Description of health condition studied

Orthopedic postoperative care

#### ICD-10 code

Z47.8

#### ICD-10 code description

Other specified orthopaedic follow-up care

## Primary outcomes

### 1

#### Description

Callus formation

#### Timepoint

Three months after surgery

#### Method of measurement

Radiography

### 2

#### Description

Postoperative infection

#### Timepoint

Monthly postoperative examinations for three months

#### Method of measurement

Physical examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients who use a digital weight-bearing control device embedded on a cane or shoe after lower extremities orthopedic surgery.

**Category**

Rehabilitation

**2**

**Description**

Control group: Patients who use a ordinary cane or shoes after lower extremities orthopedic surgery.

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Rasoul Akram hospital

**Full name of responsible person**

Mehdi Moghtadaei

**Street address**

Rasoul Akram hospital, Niyayesh St, Sattarkhan St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1465613131

**Phone**

+98 21 6435 9260

**Email**

mmoghtadaei@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Hossein keyvani

**Street address**

Iran University of Medical Sciences, Shahid Hemmat highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 8670 2503

**Email**

research-m@iums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Iran 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Alireza Amanollahi

**Position**

PhD candidate

**Latest degree**

Master

**Other areas of specialty/work**

Epidemiology

**Street address**

Rasoul Akram hospital, Niyayesh St, Sattarkhan St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 6653 9260

**Email**

amanollahi.a@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Mehdi Moghtadaei

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

**Street address**

Rasoul Akram hospital, Niyayesh St, Sattarkhan St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 6653 9260

**Email**

mmoghtadaei@gmail.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Sahand Cheraghi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

**Street address**

Rasoul Akram hospital, Niyayesh St, Sattarkhan St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

009866539260

**Email**

sahand.cheraghi@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

Finding of the study, demographic data of participants in the study, in addition to descriptive and analytical analysis of variables.

### When the data will become available and for how long

Availability six months after the end of study

### To whom data/document is available

Orthopedics

### Under which criteria data/document could be used

Anyone who has a request for information about the results of this research

### From where data/document is obtainable

Iran University of Medical Sciences

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

By referring to the central library and clinical trial center in Iran University of Medical Sciences can access to the documents of participants, data and results.

### Comments