

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

۱۳۳۹۶۱۴۵۳۵

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 an 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