

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of a new silicone mold for dynamic spacer production during knee surgery: a pilot clinical trial study

Protocol summary

Study aim

Clinical evaluation of a new silicone mold for producing dynamic spacers during knee surgery

Design

The clinical trial has a control group and a parallel group that is double-blind and non-randomized and the patients are matched. The patients are followed up for one year after the operation, and the range of motion of the knee, the level of function and diagnostic biomarkers of infection are measured in the time intervals of 1 month, 3 months, 6 months and 1 year after the operation.

Settings and conduct

The study is conducted in the hospitals of Bojnurd, the patients are divided into two groups, these groups are matched in terms of age, sex, weight and co-morbidities. The study is double-blind, and a person who does not know the type of spacer used for the patient will perform examinations and measurement of variables.

Participants/Inclusion and exclusion criteria

Entry criteria: patients with artificial joint infection. The diagnostic criteria for current knee infection for inclusion in this study are one or more of the following: aspiration of infectious synovial fluid (determined by differential count of the number of white blood cells and the percentage of polymorphonuclear leukocytes), isolation of organism(s) from synovial fluid, presence of a draining sinus, or MRI evidence of a septic arthritis with osteomyelitis. Exit criteria: None

Intervention groups

The patients are divided into two groups, one receives spacers produced manually, these spacers are made manually from bone cement and antibiotics. And the other group receives the spacers that were produced with a mold, antibiotic cement will be poured into this device and after forming, it will be placed in the knee space during surgery.

Main outcome variables

physical function and life quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191111045400N2**

Registration date: **2023-07-12, 1402/04/21**

Registration timing: **prospective**

Last update: **2023-07-12, 1402/04/21**

Update count: **0**

Registration date

2023-07-12, 1402/04/21

Registrant information

Name

Mohammad Amin Younesieh Heravi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3229 7182

Email address

a.younessi7@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of a new silicone mold for dynamic spacer production during knee surgery: a pilot clinical trial study		Postal code 74877-94149
Public title Clinical trial of a new silicone mold for dynamic spacer production during knee surgery: a pilot clinical trial study		Approval date 2023-07-05, 1402/04/14
Purpose Treatment		Ethics committee reference number IR.NKUMS.REC.1402.056
Inclusion/Exclusion criteria Inclusion criteria: aspiration of infectious synovial fluid from patient (determined by differential count of the number of white blood cells and the percentage of polymorphonuclear leukocytes) isolation of organism(s) from synovial Fluid of patient presence of a draining sinus MRI evidence of a septic arthritis with osteomyelitis Exclusion criteria: polyarticular joint involvement		Health conditions studied 1 Description of health condition studied Prosthetic Joint Infection ICD-10 code T84.5 ICD-10 code description Infection and inflammatory reaction due to internal joint prosthesis
Age No age limit		Primary outcomes 1 Description physical function Timepoint 1 month, 3 months, 6 months and one year after surgery Method of measurement They are scored through the WOMAC Score questionnaire and the Oxford Knee Score questionnaire.
Gender Both		
Phase N/A		
Groups that have been masked • Investigator		
Sample size Target sample size: 7		
Randomization (investigator's opinion) Not randomized		
Randomization description		
Blinding (investigator's opinion) Double blinded		
Blinding description A person who does not know the type of spacer used for the patient will perform examinations and measurement of variables.		
Placebo Not used		
Assignment Parallel		
Other design features		
Secondary Ids empty		
Ethics committees 1 Ethics committee Name of ethics committee Ethics committee of North Khorasan University of Medical Sciences Street address Daneshgah Ave, Imam Ali hospilat City Bojnurd Province North Khorasan		Secondary outcomes empty Intervention groups 1 Description Intervention group: The group that has spacers that were produced with a mold, In order to use this device in surgery, after sterilization, antibiotic cement is poured into it and after forming, it is placed in the knee space during surgery. Category Treatment - Surgery 2 Description Control group: The group that has manually produced spacers, usually the surgeon makes these spacers manually from bone cement and this bone cement is impregnated with antibiotics. Category Treatment - Surgery
		Recruitment centers

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Recruitment center

Name of recruitment center

Imam Ali bojnurd Hospital

Full name of responsible person

Dr Reza Ganji

Street address

Daneshghah Ave, Imam Ali Hospital

City

Bojnurd

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North Khorasan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Dr Bibak

Street address

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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

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Mohamad Aamin Younessi

Position

consultant

Latest degree

Ph.D.

Other areas of specialty/work

Medical Physics

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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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

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

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

Only research results can be shared

When the data will become available and for how long

beginning of year 2024

To whom data/document is available

just for researchers

Under which criteria data/document could be used

no conditions required

From where data/document is obtainable

to the phone number inserted

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

almost one week

Comments