

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Effect of Pulsed Electromagnetic Field on clinical evaluation and quality of life of patient with knee hemophilic arthropathy

#### Protocol summary

##### Study aim

The effect of pulsed electromagnetic fields on clinical symptoms and quality of life in the patients with knee hemophilic arthropathy

##### Design

This study is a single blinded randomized controlled trial with parallel group. Sampling method is simple probability and grouping method is based on simple randomized allocation method (using random-numbers table method) and the sample size is 40 hemophila patients.

##### Settings and conduct

The study will be done in Isfahan province hemophilia center. The volunteers will be examined by a specialist and will be included in the study if they have defined inclusion criteria. Then, they will be referred to the radiologist to determine the severity of the knee joint hemophilic arthropathy, then the subjects randomly will be divided into treatment and control groups. The treatment group receives pulsed electromagnetic field for one hour, and the control group is placed under the same program while the device is turned on and the output is zero. Knee clinical symptoms and quality of life of the patients will be measured before and after 18 sessions by a physiotherapist.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria 1. The men with severe hemophilia A 2. The age range should be 20-40 years 3. Having at least one knee joint with active synovitis Exclusion criteria 1. Having a body mass index more than 30 kg/m<sup>2</sup> 2. Having a heart pacemaker

##### Intervention groups

Intervention group: Pulsed electromagnetic field for one hour Control group: Pulsed electromagnetic field while the output of the device is zero for one hour

##### Main outcome variables

Knee joint clinical symptoms; Quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180716040488N1**

Registration date: **2018-09-26, 1397/07/04**

Registration timing: **retrospective**

Last update: **2018-09-26, 1397/07/04**

Update count: **0**

##### Registration date

2018-09-26, 1397/07/04

##### Registrant information

##### Name

Azam Khami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3237 3579

##### Email address

khami@med.mui.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-08-11, 1397/05/20

##### Expected recruitment end date

2018-09-16, 1397/06/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Pulsed Electromagnetic Field on clinical evaluation and quality of life of patient with knee hemophilic arthropathy

#### Public title

Effect of Magnet on clinical evaluation and quality of life in knee hemophilic arthropathy

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Men with severe hemophilia A Having at least one knee joint with active synovitis The Pettersson radiographic score of patients should be 5-9 The age range should be 20-40 years

##### Exclusion criteria:

Body Mass Index > 30 kg/m<sup>2</sup> Having a heart pacemaker Having a history of surgery or intra-articular injection of the knee in the last 6 months Performing knee physiotherapy in the past month Performing knee joint replacement therapy

#### Age

From **20 years** old to **40 years** old

#### Gender

Male

#### Phase

N/A

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **40**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Patients are selected using the simple random method. The participants are randomly divided into two equal groups by random-numbers table.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

The participants are not aware of the electromagnetic device being on and off.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

###### Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi Street, Shahid Chamran Highway, Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

1985717443

#### Approval date

2018-09-25, 1397/07/03

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1397.547

### Health conditions studied

#### 1

##### Description of health condition studied

Hemophilic arthropaty in hemophilia Patients

##### ICD-10 code

D66

##### ICD-10 code description

Hereditary factor VIII deficiency

### Primary outcomes

#### 1

##### Description

The Score of Hemophilia joint Health Score (HJHS) questionnaire

##### Timepoint

At the beginning and end of the study

##### Method of measurement

Hemophilia Joint Health Score (HJHS) questionnaire

#### 2

##### Description

The score of the quality of life questionnaire A36 Hemofilia -Qol

##### Timepoint

At the beginning and end of the study

##### Method of measurement

Using a quality of life questionnaire A36 Hemofilia -Qol

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: Patients with knee joints exposed to Pulsed Electromagnetic Field, for 60 minutes, at frequencies of 2 Hz and 70 Hz

##### Category

Treatment - Devices

## 2

### Description

Control group: Patients with knee joints exposed to Pulsed Electromagnetic Field, for 60 minutes, at frequencies of 2 Hz and 70 Hz while the output of the device is zero

### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Esfahan hemophilia center

##### Full name of responsible person

Malihe Afzali

##### Street address

No 196, Nahid Dead End, Next to Footbridge, In front of Seyedo shohada Hospital, Motahari Street

##### City

Esfahan

##### Province

Isfahan

##### Postal code

8184914711

##### Phone

+98 31 3235 4343

##### Fax

+98 31 3235 4343

##### Email

infohemofilia1377@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Alireza Akbarzadeh Baghbane

##### Street address

Opposite to Booali Hospital, Damavand Ave, Shaheed Bakhshifard St. School of Rehabilitation

##### City

Tehran

##### Province

Tehran

##### Postal code

1616913111

##### Phone

+98 21 7754 2057

##### Fax

+98 21 7759 1807

##### Email

roosta@sbmu.ac.ir

##### Web page address

<http://rehab.sbmu.ac.ir/>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahid Beheshti 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

Azam Khami

##### Position

MSc

##### Latest degree

Master

##### Other areas of specialty/work

Physiotherapy

##### Street address

Opposite to Booali Hospital, Damavand Ave, Shaheed Bakhshifard St. School of Rehabilitation

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##### Province

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+98 21 7759 1807

##### Email

Khamiazam@gmail.com

##### Web page address

<http://rehab.sbmu.ac.ir/>

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Mohammad Mohsen Roostayi

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Physiotherapy  
**Street address**  
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roosta@sbmu.ac.ir  
**Web page address**  
<http://rehab.sbmu.ac.ir/>

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Azam Khami  
**Position**  
Master of science  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Physiotherapy  
**Street address**  
Apartment 4, Plate No.22, Bagh-janat Alley, Abouzar  
Street, Abbas Abad Street  
**City**  
Esfahan  
**Province**  
Isfahan

**Postal code**  
8133746851  
**Phone**  
+98 31 3237 3579  
**Email**  
khamiazam@gmail.com

## 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

Not applicable

### Data Dictionary

Not applicable

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

demographic information of participants

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

After the end of the study

### To whom data/document is available

Investigators

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

For checking the accuracy of the study, and also, design of other studies

### From where data/document is obtainable

Scientific manager of the study

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

Connect by email

### Comments