Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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/m2 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/m2 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 Ayatolah 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

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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

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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

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

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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

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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
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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
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