Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

The efficacy of prophylactic treatment with coagulation factores in reducing the frequency of joint/non-joint bleedingand the consumption of coagulation factor in under 15 year old patients with severe A hemophilia

Protocol summary

Study aim

To evaluate the efficacy of preventive treatment with coagulation factors on number of joint/ non-joint bleeding and the consumption of coagulation factor

Design

In this research, 12 patients with severe A hemophilia referring to comprehensive Hemophilia clinic of Imam Khomeini Hospital Complex will be selected purposefully. The participants will be selected successively and sampling will continue to reach the desired number.

Settings and conduct

First, an inhibitor level test will perform. In the cases have negative inhibitor level, a prophylactic treatment with factor VIII (at least 20 units per kg once a week and maximum 30 units per kg, three times per week) based on the severity of joint destruction and repetitive joint bleeding will be done. Study will be performed at comprehensive Hemophilia clinic of Imam Khomeini Hospital Complex. The study is not blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Negative antibody level; Factor VIII less than 1% Exclusion criteria: Age over 15 years; Presence of an inhibitor in blood

Intervention groups

First group (No bleeding in soft/articular tissue): No action The second group (Patients who have had at least one bleeding in soft or articular tissue that has not received a coagulation factor till now): Start dose: 25 units per kg once a week, first stage of positive change: 25 units per kg twice a week, second stage of positive change: 25 units per kg three times a week The third group (Patients who have surely received more than 50 days of coagulation factor): Start dose: 25 units per kg once a week, first stage of positive change: 25 units per kg twice a week, second stage of positive change: 25 units per kg three times a week The fourth group (Patients who have, or have probably, received less than 50 days of coagulation factor): Start dose: 50 units per kg once a week, first stage of positive change: 30 units per kg twice a week, second stage of positive change: 25 units per kg three times a week The program continues at start dose and the change to the first and second stages depends on the occurrence of one of the following conditions: • Incidence of 3 joint bleeding during the last three months of current prevention program • Incidence of 4 major soft tissue bleeding during the last three months of current prevention program • The occurrence of a dangerous and important bleeding without trauma or side effect despite of current prevention program. In other words, dose changes from the start dose to the first stage, and from the first to the second stage, occurs only in one of these situations.

Main outcome variables

the frequency of joint/ non-joint bleeding; the consumption of coagulation factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170211032495N1**
Registration date: **2018-01-17, 1396/10/27**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-17, 1396/10/27**
Update count: **0**

Registration date

2018-01-17, 1396/10/27

Registrant information

Name

Katayoon Karimi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2018-01-04, 1396/10/14

Expected recruitment end date

2019-01-04, 1397/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of prophylactic treatment with coagulation factores in reducing the frequency of joint/non-joint bleedingand the consumption of coagulation factor in under 15 year old patients with severe A hemophilia

Public title

The effect of coagulation factors on the reduction of joint/ non-joint bleeding and the consumption of coagulation factor in patients with severe A hemophilia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Negative antibody Factor VIII less than 1%

Exclusion criteria:

Age over 15 years Presence of an inhibitor

Age

From **12 months** old to **15 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Central building of Tehran University of Medical Sciences, Qods street, Keshavarz Boulevard.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2015-11-21, 1394/08/30

Ethics committee reference number

IR.TUMS.REC.1394.1204

Health conditions studied

1

Description of health condition studied

Hemophilia

ICD-10 code

D66

ICD-10 code description

Hereditary factor VIII deficiency

Primary outcomes

1

Description

Joint/ non-joint Bleeds

Timepoint

Before the intervention and 6 months after the intervention

Method of measurement

Factor VIII test

2

Description

Consumption of coagulation factor

Timepoint

Before the intervention and 6 months after the intervention

Method of measurement

Counting the number of used vials

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: Patients with at least one bleeding in soft or articular tissue that have not received coagulation factor: Start dose: 25 units per kg factor VIII once a week, first stage of positive change: 25 units per kg twice a week, second stage of positive change: 25 units per kg three times a week
Category
Prevention

2

Description
Second intervention group: Patients who have surely received more than 50 days of coagulation factor: Start dose: 25 units per kg factor VIII once a week, first stage of positive change: 25 units per kg twice a week, second stage of positive change: 25 units per kg three times a week
Category
Prevention

3

Description
Third intervention group: Patients who have, or have probably, received less than 50 days of coagulation factor: Start dose: 50 units per kg factor VIII once a week, first stage of positive change: 30 units per kg twice a week, second stage of positive change: 25 units per kg three times a week
Category
Prevention

4

Description
Control group: Patients without bleeding in soft/articular tissue): No action
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
Dr. Katayoon Karimi
Street address
Imam Khomeini Hospital Complex, The end of Keshavarz boulevard, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Tehran University of Medical Sciences
Full name of responsible person
Dr. Masoud Younesian
Street address
Central building of Tehran University of Medical Sciences, Qods Street, Keshavarz Boulevard.
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Email
Dr.karimi70@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Tehran 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
Imam Khomeini Hospital Complex
Full name of responsible person
Dr. Katayoon Karimi
Position
Specialist for thrombosis and homeostasis
Latest degree
Specialist
Other areas of specialty/work

thrombosis and hemostasis

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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
Not applicable

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
The main outcomes' data, including testing, interventions and results of intervention will be shared .

When the data will become available and for how long
Access starts after the publication of the results.

To whom data/document is available
Researchers of academic institutions

Under which criteria data/document could be used
Presenting a Introduction letter from the University

From where data/document is obtainable
E-mail: dr.karimi70@gmail.com Dr. Katayun Karimi

What processes are involved for a request to access data/document
After receiving the request and the introduction letter, Tehran University of Medical Sciences will get permission and the file will be sent to them.

Comments