

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparing the cost-effectiveness of two alternative bypassing agents (aryoseven & feiba) for patients with hemophilia A complicated by an inhibitor in Iran

Protocol summary

Summary

Hemophilia is a bleeding disorder caused by a deficiency or absence of blood coagulation factors and inherited genetic cause of the disease is concerned, and the lifetime. The most common types of hemophilia A and B, which are caused due to deficiency of clotting factor 8 or 9 and have different treatment protocols. As a result, if inhibitor with high titer ($> 5\text{BU}$) forced to use drugs as a factor of seven recombinant (rFVIIa) brand AryoSeven or Factor VIII (brand FEIBA) for the treatment to be in this study to determine the cost of different strategies for treatment of hemophilia, the analysis of cost - effectiveness will be used. This study is based on data available to assess the cost - effectiveness of the Factor 8 clotting and 7 recombinant used in the subsidy considerable time to account for the present study, two types of data need data cost and data patients received a weight basis, the price of coagulation factors, use of other medications, hospitalization costs, costs of diagnostic and general medical costs and other costs are taken into account. To determine the effects of treatment, patients were classified into three groups based on the treatment believe (according to the questionnaire) are divided into consumer Aryo (Group A), consumers Feiba (Group F) both consumers (with no or new) (Group O)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013020612380N1**

Registration date: **2013-05-07, 1392/02/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-07, 1392/02/17

Registrant information

Name

Mina Golestani

Name of organization / entity

Faculty of pharmacy, Shahid Beheshti University of Medical Sciences)

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 2291

Email address

mgolestani8958@gmail.com

Recruitment status

Recruitment complete

Funding source

Aryogen Biopharma

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the cost-effectiveness of two alternative bypassing agents (aryoseven & feiba) for patients with hemophilia A complicated by an inhibitor in Iran

Public title

Comparing the cost-effectiveness of two alternative bypassing agents (aryoseven & feiba)for haemophilia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with severe hemophilia a with high inhibitor titers (greater than or equal to 5 Bethesda) in pilot studies to assess the attitude of coagulation shortcuts are classified. Exclusion criteria: patients who have previously unclassified; patients with coagulation problems, developed liver problems; patients who received coagulation products is over 5 days ago and patients who have bleeding arthritis in the joint within 7 days ago.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

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

congenital blood disease research/Shahid Beheshti
University of Medical Sciences

Street address

Mofid Children's Hospital

City

tehran

Postal code

0098

Approval date

2013-02-03, 1391/11/15

Ethics committee reference number

1391-1-168-1054

Health conditions studied

1

Description of health condition studied

Haemophilia

ICD-10 code

D66

ICD-10 code description

Hereditary factor VIII deficiency

Primary outcomes

1

Description

Pain

Timepoint

1, 3, 6, 9 and 12 hours after intervention

Method of measurement

Measure kavakli

2

Description

Range of motion

Timepoint

1, 3, 6, 9 and 12 hours after intervention

Method of measurement

Measure kavakli

Secondary outcomes

1

Description

bleeding control

Timepoint

24 hours

Method of measurement

Evaluation of treatment success

Intervention groups

1

Description

Intervention group1: patients based on the belief treatment & based on previous history (questionnaire available) are divided into consumer Aryo (Group A), two bleeding event in each category will be discussed.(which is a very important factor in the effectiveness of treatment and could be confounding factors in most studies, it is not accurate) and medication requirements, and form of CRF (monitoring symptoms during 1,3,6,9,12) will be delivered. Protocol A • Injection Dosage: The dose of 90-120 mg / kg body weight (mean 100 mg / kg body weight) • Injection time - 0 hours and 3 - 6 pm If pain assessment and limitations Moving clocks 3 and 6 are both negative dose of 270 mg / kg injection - at 9 or 12 for the assessment of pain and limitations of movement is negative, just one more dose of 270 mg / kg injections (up to 2 times per stroke, bleeding dosage 3 to be given).

Category

Treatment - Drugs

2**Description**

Intervention group 2: Patient care based on the belief & treatment history (according to the questionnaire) will be divided into consumer Faiba (Group F): 2 bleeding event in each category will be discussed 1,3,6,9,12) will be delivered. Protocol F (Appendix Figure 2): • First dose at zero time :50-75 units / kg body weight • Second dose at 9 pm only if both pain and limitation of movement in 6 and 9pm are negative (no improvement in 6 hours Recent or severe pain 9) with 75 to 100 units / kg will repeat. • * If both protocols is less than 8 out of the 12 hours following drug treatment will change, but the calculation model, the drug has no further role

Category

Treatment - Drugs

3**Description**

Control group: because of consistency of study the patients are divided into control group(O) Indifferent or new

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Haemophilia clinic in mofid hospital

Full name of responsible person

Dr. Peyman Eshghi

Street address**City**

Tehran

2**Recruitment center****Name of recruitment center**

Haemophilia clinic of Imam Khomeini hospital

Full name of responsible person

Dr. Mohammad Reza Managhchi

Street address

Imam Khomeini hospital,Tehran

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Aryogen biopharma co.

Full name of responsible person

Dr.Babak Khoein

Street address

Cross Tajbakhsh Street, 24th Kilometer Makhsous,
Tehran - Iran . AryoGen Biopharma Co.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Aryogen biopharma co.

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mina Golestani

Position

PhD candidate(Pharmacoeconomics &
Pharmaceutical Management)

Other areas of specialty/work**Street address**

Pharmacy faculty, Shahid Beheshti University of
Medical Sciences,Tehran

City

Tehran

Postal code**Phone**

+98 41 1336 6290

Fax**Email**

mgolestani8958@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Peyman Eshghi

Position

Blood Diseases Pediatric specialist

Other areas of specialty/work**Street address**

Haemophilia Clinic of mofid Children hospital

City

Tehran

Postal code

Phone

+98 21 2290 4536

Fax

Email

peyman64@yahoo.com

Web page address

City

Tehran

Postal code

Phone

+98 41 1336 6290

Fax

Email

Web page address

Sharing plan

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mina Golestani

Position

PhD candidate(Pharmacoeconomics & Pharmaceutical Management)

Other areas of specialty/work

Street address

Pharmacy faculty, Shahid Beheshti University of Medical Sciences,Tehran

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty