Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 (> 5BU) 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

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Name of organization / entity

Faculty of pharmacy, Shahid Beheshti University of Medical Sciences)

Country

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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)
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Sharing plan

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