

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

The evaluation efficacy of Desmopressin (1-deamino-8-D arginine Vasopressin) in increasing coagulation factor V and VIII in patients with combined factor V and VIII deficiency.

Protocol summary

Summary

Aim of study: Evaluation of possible usage of Desmopressin in treatment of the patients with combined factor V and VIII deficiency. Design of procedure of the study: Owing to combined factor V and VIII deficiency is rare disorder, all anciently recognized patients with 24 cases with combined factor V and VIII deficiency, were invited to accompanying in the study and after their agreements and signing informed consent forms and also applying inclusion and exclusion criteria, 20 cases were entered to the survey. At first, the patients were admitted to hematology department in hospital and a blood sample for determination of plasma levels of factor V and VIII was obtained and one hour after infusion of vasopressin, the second blood sample was obtained to determine possible elevation of coagulation factors V and VIII. The study method including: A) Population under study: 24 cases with combined factor V and VIII deficiency. Inclusion criteria: Confirmed affection with combined factor V and VIII deficiency using an identification card of hemophilia center or coagulation laboratory sheet showing diagnosis of combined factor V and VIII deficiency; Having more than 18 years old officially; Agreement to accompanying in research and signing informed consent form after auscultation details and process of blood sampling and blood volume; No infusion of factor VIII during last 48 hours; No infusion of fresh frozen plasma or cryoprecipitate during last 48 hours; Not having active bleeding in time of accompanying in research; Exclusion criteria: Affection to other similar coagulation disorders, inter alia, combined factor VIII & IX deficiency; Having less than 18 years old officially; No agreement to accompanying in research and or signing informed consent form after auscultation details and process of blood sampling and blood volume; Infusion of factor VIII during last 48 hours; Infusion of fresh frozen plasma or

cyoprecipitate during last 48 hours; Having active bleeding in time of accompanying in research; Sample size: 24 cases that after applying inclusion and exclusion criteria, 20 cases entered the study. Intervention: Infusion of 0.4 microgram/Kg of Desmopressin Acetat (1-deamino-8-D arginine Vasopressin) using 50 CC of normal saline 0.9% by intravenous route. Time of intervention: After sampling first blood sample. Primary outcome or studied outcomes: Possible elevation of coagulation factors V and VIII in one hour after Desmopressin. The current study was designed as before & after method. At first the levels of coagulation factors V and VIII will be measured then Desmopressin drug will be infused and after passing an hour the levels of factors V and VIII will be assayed to determine their possible effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015020120894N1**

Registration date: **2015-04-25, 1394/02/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-04-25, 1394/02/05

Registrant information

Name

Hassan Mansouritorghabeh

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2830

Email address mansouritorghabeh@mums.ac.ir	Groups that have been masked No information
Recruitment status Recruitment complete	Sample size Target sample size: 24
Funding source The financial expenses of current research was covered by vice chancellor for research in Mashhad University of Medical Sciences and Kedrion Company devoted needed drug free of charge to researchers.	Randomization (investigator's opinion) Not randomized
	Randomization description
	Blinding (investigator's opinion) Not blinded
	Blinding description
	Placebo Not used
	Assignment Single
	Other design features
Expected recruitment start date 2009-11-20, 1388/08/29	Secondary Ids empty
Expected recruitment end date 2010-09-20, 1389/06/29	Ethics committees
Actual recruitment start date empty	1
Actual recruitment end date empty	Ethics committee
Trial completion date empty	Name of ethics committee National ethics committee in biological sciences
Scientific title The evaluation efficacy of Desmopressin (1-deamino-8-D arginine Vasopressin) in increasing coagulation factor V and VIII in patients with combined factor V and VIII deficiency.	Street address 15th floor, Treatment and medical education, Research & Technology assistance, Main center of Ministry of Health, Treatment and Medical education, Simaie Iran Street, Between Southern Flamak and Zarafshan, Ghods city (West)
Public title The evaluation efficacy of Desmopressin in improvement coagulation status of patients with combined factor V and VIII deficiency.	City Tehran
Purpose Treatment	Postal code 1445382774
Inclusion/Exclusion criteria Inclusion criteria: Confirmed affection with combined factor V and VIII deficiency using an identification card of hemophilia center or coagulation laboratory sheet showing diagnosis of combined factor V and VIII deficiency; Having more than 18 years old officially; Agreement to accompanying in research and signing informed consent form after auscultation details and process of blood sampling and blood volume; Not infusion of factor VIII during last 48 hours; Not infusion of fresh frozen plasma or cryoprecipitate during last 48 hours; 6-Not having active bleeding in time of accompanying in research. Exclusion criteria: 1-Affection to other similar coagulation disorders, inter alia, combined factor VIII & IX deficiency. 2-Having less than 18 years old officially. 3-Not agreement to accompanying in research and signing informed consent form after auscultation details and process of blood sampling and blood volume. 4-Infusion of factor VIII during last 48 hours. 5-Infusion of fresh frozen plasma during last 48 hours. 6-Having active bleeding in time of accompanying in research.	Approval date 2009-10-12, 1388/07/20
Age From 18 years old to 100 years old	Ethics committee reference number 41-588/پ
Gender Both	2
Phase 2	Ethics committee
	Name of ethics committee Regional ethics committee in Mashhad University of Medical Sciences
	Street address Ethics committee office, 2nd floor, Ghoreishi Building, Daneshgah Street
	City Mashhad
	Postal code 91766-99199
	Approval date 2007-12-16, 1386/09/25
	Ethics committee reference number 86029

Health conditions studied

1

Description of health condition studied

Combined factor V and VIII deficiency

ICD-10 code

D68.2

ICD-10 code description

Hereditary deficiency of other clotting factors

Primary outcomes

1

Description

Plasma level of coagulation factor V

Timepoint

One hour after termination of DDAVP injection

Method of measurement

According to standard one-stage APTT method

2

Description

Plasma level of coagulation factor VIII

Timepoint

One hour after termination of DDAVP injection

Method of measurement

According to standard one-stage APTT method

Secondary outcomes

1

Description

Flushing

Timepoint

One hour after injection of Desmopressin

Method of measurement

Appearance of flushing in face and feeling of warmth by the patients

Intervention groups

1

Description

Injection of 0.4 micrograms per kilogram of body weight (mcg/kg) of Desmopressin by 50 ml of 0.9% sodium chloride via intra-venous route over period of 20 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hematology ward, Ghaem hospital

Full name of responsible person

Dr. Abbas Shirdel

Street address

Hematology ward, Ghaem hospital

City

Mashhad

2

Recruitment center

Name of recruitment center

Allergy/Immunology Research Center

Full name of responsible person

Hassan Mansouritorghabeh

Street address

Allergy ward, 3rd floor, Ghaem Hospital

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr. Saieed Eslami

Street address

Research Managment, Ghoreieshi Building, Daneshgah Street

City

Mashhad

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, Mashhad University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Kedrion

Full name of responsible person

Lorenzo Morini

Street address

Castelvecchio Pascoli Loc, Ai Conti 55051

City

Barga

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kedrion

Proportion provided by this source

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

Mashhad University of Medical Sciences

Full name of responsible person

Hassan Mansouritorghabeh

Position

MSc in hematology and PhD student

Other areas of specialty/work

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Full name of responsible person

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Person responsible for updating data

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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