

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 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

**Recruitment status**

**Recruitment complete**

**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.

**Expected recruitment start date**

2009-11-20, 1388/08/29

**Expected recruitment end date**

2010-09-20, 1389/06/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**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.

**Public title**

The evaluation efficacy of Desmopressin in improvement coagulation status of patients with combined factor V and VIII deficiency.

**Purpose**

Treatment

**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.

**Age**

From **18 years** old to **100 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

National ethics committee in biological sciences

**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)

**City**

Tehran

**Postal code**

1445382774

**Approval date**

2009-10-12, 1388/07/20

**Ethics committee reference number**

41-588/پ

**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**

**Street address**

Allergy ward, 3th floor, Ghaem hospital

**City**

Mashhad

**Postal code**

91766-99199

**Phone**

+98 51 3801 2830

**Fax**

+98 51 3842 2544

**Email**

mansouritorghabeh@mums.ac.ir

**Web page address**

www.mums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hassan Mansouritorghabeh

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**Web page address**

www.mums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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**Web page address**

www.mums.ac.ir

**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*