

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Evaluation of the prophylactic effect of tranexamic acid in von willebrand disease and glanzman thrombasthenia

#### Protocol summary

##### Summary

Objectives: evaluation of the prophylactic effect of tranexamic acid in von willebrand disease and glanzman thrombasthenia. Design: This study is a double-blind, before after clinical trial. sampling method is a simple Non-probability. Setting and conduct: All patients with a diagnosis of von Willebrand and Glanzmann thrombasthenia that refer to Hemophilia Clinic of Amir-Kabir hospital enter to the study that the number of about 20 people. The 20 patients for six months use tranexamic acid capsules that filled with starch as placebo and record the bleeding frequency and severity, and the frequency of used concentrate. After six months, patients treated with tranexamic acid capsules manufactured by Amin-drug, daily 25 mg per kilogram of body up to 500 mg placed in a single dose, and again record the bleeding frequency and severity, and the frequency of used concentrate. So each patient is yourself control. Data recording done by second performer that have not any information about that used drug is real or the placebo. The information collecting is based on observation and questionnaire. Inclusion criteria: All patients with a von Willebrand I, II, III and Glanzmann thrombasthenia which they records are included in Arak Amir-Kabir Hospital. Exclusion criteria: (a)Patients who have a history of thrombosis (b)Patients who do not consent to the inclusion (c)Patients with hepatitis B or C (d)Patients with liver or renal dysfunction (e)Patients with local bleeding lesions such as hemangiomas or local wound (f)Younger than 2 years (g)Patients who can not tolerate the gastrointestinal drug

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015111525031N2**

Registration date: **2015-12-05, 1394/09/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-12-05, 1394/09/14

##### Registrant information

###### Name

Fatemeh Rafiei

###### Name of organization / entity

Arak University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3226 5732

###### Email address

a.rafeei@tafreshu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Arak University of Medical Sciences

##### Expected recruitment start date

2014-07-23, 1393/05/01

##### Expected recruitment end date

2015-07-23, 1394/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the prophylactic effect of tranexamic acid in von willebrand disease and glanzman thrombasthenia

##### Public title

Evaluation of the prophylactic effect of tranexamic acid in von willebrand disease and glanzman thrombasthenia

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

Inclusion criteria: All patients with a von Willebrand I, II, III and Glanzmann thrombasthenia which they records are included in Arak Amir-Kabir Hospital.; Exclusion criteria: (a)Patients who have a history of thrombosis; (b)Patients who do not consent to the inclusion; (c)Patients with hepatitis B or C; (d)Patients with liver or renal dysfunction; (e)Patients with local bleeding lesions such as hemangiomas or local wound; (f)Younger than 2 years; (g)Patients who can not tolerate the gastrointestinal drug;

### **Age**

From **2 years** old to **139 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **20**

### **Randomization (investigator's opinion)**

N/A

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Single

### **Other design features**

Our study is a before after clinical trial, and sampling method is a simple Non-probability.

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committe of Arak University of Medical Sciences

##### **Street address**

Basij Square, Sardasht, Arak, Iran

##### **City**

Arak

##### **Postal code**

#### **Approval date**

2014-07-14, 1393/04/23

#### **Ethics committee reference number**

6-165-93

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Glanzmann thrombasthenia

#### **ICD-10 code**

D69.1

#### **ICD-10 code description**

Qualitative platelet defects

### 2

#### **Description of health condition studied**

Von Willebrand

#### **ICD-10 code**

D68.0

#### **ICD-10 code description**

Von Willebrand disease

## **Primary outcomes**

### 1

#### **Description**

The number of bleeding attacks

#### **Timepoint**

before and six months after intervention

#### **Method of measurement**

counting frequency

### 2

#### **Description**

The severity of bleeding

#### **Timepoint**

before and six months after intervention

#### **Method of measurement**

visual scale and assigned a grade from one to four

### 3

#### **Description**

The number of used concentrates

#### **Timepoint**

before and six months after intervention

#### **Method of measurement**

counting frequency

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

for six months, patients treated with tranexamic acid capsules manufactured by Amin-drug, daily 25 mg per kilogram of body up to 500 mg placed in a single dose

#### **Category**

Treatment - Drugs

## 2

### Description

for six months use tranexamic acid capsules that filled with starch as placebo

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hemophilia Clinic of Amir-Kabir Hospital

##### Full name of responsible person

Dr. Laura Melikof

##### Street address

Amir-Kabir Hospital, Parastar Square, Arak, Iran

##### City

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research of Arak University of Medical Sciences

##### Full name of responsible person

Dr. Laura Melikof

##### Street address

Amir-al-Momenin Hospital, Basij Square, Sardasht, Arak, Iran

##### City

Arak

#### 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 Arak University of Medical Sciences

#### 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

Arak University of Medical Sciences

#### Full name of responsible person

Dr. Laura Melikof

#### Position

Professional Doctorates, Pediatric Assistant

#### Other areas of specialty/work

#### Street address

Pardis Complexes, Bo-ali Street, Arak, Markazi, Iran

#### City

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#### Postal code

3819797457

#### Phone

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#### Fax

#### Email

sun14039@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Arak University of Medical Sciences

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Dr. Laura Melikof

#### Position

Professional Doctorates, Pediatric Assistant

#### Other areas of specialty/work

#### Street address

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## Person responsible for updating data

### Contact

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**Email**  
sun14039@yahoo.com  
**Web page address**

## 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*