Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
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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
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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