

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of tranexamic acid on postpartum hemorrhage of natural delivery in Shariati hospital (2014-15):

Protocol summary

Summary

Effect of tranexamic acid on postpartum hemorrhage of natural delivery in Shariati hospital (2014-15): Purpose of the study: this research aimed to investigate the effect of tranexamic acid on postpartum blood loss through natural delivery in Shariati hospital (2014-15). Design: the research population consisted of all pregnant women visiting shariati instructional hospital in bandar abbass who opted for a natural delivery. The treatment group and the control in the sample each consisted of 120 participants. This randomized clinical trial was controlled and double-blinded. Methods: The present case-control research explored the effect of intravenous tranexamic acid (1g). Therefore, 1 g of the acid (in 200 mL of normal saline) was given to the treatment group while the control received a placebo (distilled water in 200 mL of normal saline). Immediately after the emergence of placenta, both groups received 20 units of oxytocin solved in 500 mL of normal saline in 20 minutes. Blood sample tests were taken from the participants once 1-12 hours prior to the childbirth and once again 12-24 hours afterwards to measure hemoglobin and hematocrite. The inclusion criteria were pregnancy with a singleton, pregnancy age of 38-42 weeks, mother's age of 18-35 years and finally 5 years or less experience of pregnancy and normal blood pressure. The exclusion criteria were excessively long (over 13 hours) induction duration in the first phase of delivery, experience of prior c-section or uterine surgery, uterine fibroma, history of internal diseases such as cardiovascular or renal problems. The primary variable was the effect of tranexamic acid on natural delivery hemorrhage. The secondary variable was natural delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052029485N3**

Registration date: **2017-05-27, 1396/03/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-27, 1396/03/06

Registrant information

Name

Ali Safari

Name of organization / entity

School of public health, Shahid beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 3275 5043

Email address

alisafari_31@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Hormozgan University of Medical Sciences

Expected recruitment start date

2016-01-04, 1394/10/14

Expected recruitment end date

2016-04-24, 1395/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of tranexamic acid on postpartum hemorrhage of natural delivery in Shariati hospital (2014-15):

Public title

Effect of tranexamic acid on postpartum hemorrhage of natural delivery in Shariati hospital (2014-15):

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria were pregnancy with a singleton, pregnancy age of 38-42 weeks, mother's age of 18-35 years and finally 5 years or less experience of pregnancy and normal blood pressure. The exclusion criteria were excessively long (over 13 hours) induction duration in the first phase of delivery, experience of prior c-section or uterine surgery, uterine fibroma, history of internal diseases such as cardiovascular or renal problems.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **240**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences

Street address

ice chancellor for research and technology, Shahid Mohamadi Hospital

City

Bandar Abbas

Postal code

7914964157

Approval date

2015-11-23, 1394/09/02

Ethics committee reference number

HUMS.REC.1394.92

Health conditions studied

1

Description of health condition studied

delivery

ICD-10 code

o72

ICD-10 code description

postpartum haemorrhage

Primary outcomes

1

Description

Average hemorrhage

Timepoint

12-24 hours after delivery

Method of measurement

Blood samples to measure hemoglobin and hematocrit

Secondary outcomes

empty

Intervention groups

1

Description

To the control group was injected took placebo tranexamic acid (distilled water) in 200 ml of normal saline

Category

Treatment - Drugs

2

Description

To the intervention group received 1 g of tranexamic acid in 200 ml intravenous saline injections.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Dr. Ali Shariati

Full name of responsible person

Azin alavi

Street address

Bandar Abbas, hospital, doctor Ali Shariati, Shahid Nasser Blvd.

City

Bandar Abbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Hormozgan University of Medical Sciences

Full name of responsible person

Teamour aghamolaei

Street address

Vice Chancellor for research of Hormozgan University of Medical Sciences

City

Bandar abbas

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 Hormozgan 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**

Hospital Dr. Ali Shariati

Full name of responsible person

Zinab Nasiri

Position

Resident of Obstetrics and Gynecology.

Other areas of specialty/work**Street address**

Hospital Dr. Ali Shariati

City

Bandar Abbas

Postal code**Phone**

+98 917 769 0672

Fax**Email**

nasiri@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Dr.Shariati hospital

Full name of responsible person

Azin Alavi

Position

Assistant Professor

Other areas of specialty/work**Street address**

Bandar abbas

City

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Fax**Email**

azin_alavi@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Hospital Dr. Ali Shariati

Full name of responsible person

Zinab Nasiri

Position

Resident of Obstetrics and Gynecology.

Other areas of specialty/work**Street address**

Bandar Abbas, Ali Shariati hospital, Shahid Nasser Blvd.

City

Bandar Abbas

Postal code**Phone**

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Fax**Email****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