

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of oral conjugated estrogen compared with cryoprecipitate to prevent bleeding in patients with renal failure candidates for kidney biopsy

Protocol summary

Summary

Bleeding is one of the potentially dangerous and common complications in patients with acute and chronic renal failure .Bleeding from uremia is multifactorial. Impaired function of the interaction between platelets and platelets together with the vessel wall, due to the toxicity of urea in the blood, has an important role in causing the bleeding. Crayoprcipitate and estrogen conjugate in the treatment of bleeding are used. In this study the effect of estrogen in the prevention of bleeding in this patients compared with crayoprcipitate .This study initially intends complications and benefits oral estrogen compared with crayoprcipitate transfusion. In a clinical trial, the number of 30 patients with renal failure who admitted in nephrology ward and all of them candidates for biopsy selected. patients divided two groups 1)Infusion of 10 units crayoprcipitate in the morning of biopsy 2) 1.25mg estrogen TID administered than 5 days before biopsy Then each group controlled hemorrhagic complications (vital signs, hemoglobin level, hematuria sonographic control of hematoma) in the same day and the next day after the biopsy .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201028593N1**
Registration date: **2012-01-19, 1390/10/29**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-01-19, 1390/10/29

Registrant information

Name

Kaveh Ebadiborna

Name of organization / entity

jondishapour university

Country

Iran (Islamic Republic of)

Phone

+98 61 1333 8781

Email address

ebadiborna.k@ajmus.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jondishapour of Medical Science

Expected recruitment start date

2010-12-22, 1389/10/01

Expected recruitment end date

2011-12-22, 1390/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral conjugated estrogen compared with cryoprecipitate to prevent bleeding in patients with renal failure candidates for kidney biopsy

Public title

Effects of oral conjugated estrogen in preventing bleeding from renal biopsy in uremic patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with renal insufficiency

(creatinine greater than 3 mg/dL) who are candidates for biopsy Exclusion criteria: 1.Pregnant women, or women who suspect pregnancy and ways to avoid becoming pregnant to leave have 2.Lactating women 3.Patients with a history of thromboembolism 4.Any of the patients treated with anticoagulant or platelet aggregation inhibitors such as warfarin, heparin, enoxaparin, Ticlopidine, clopidogrel, and statins and their agents can not be stopped 5.Patients who are treated with NSAIDs and their agents can not be interrupted for any reason 6.Patients who have clotting disorders (such as patients with hemophilia) or in the laboratory of PT> 14, PTT> 35, or INR> 1.5 7.Patients who were under a regime of hard power (such as prolonged fasting or water treatment) and lack of essential Elements, vitamins such as vitamin C or K in the body there 8.Patients who have blood pressure higher than 160/100,before the biopsy 9.Patients with a creatinine level is less than 3 milligrams per deciliter 10.Patients who are suffering from liver cirrhosis. 11.Patients with platelet count less than 100,000 12.Patients who have cysts in both kidney 13.Patients who have undergone kidney transplant 14.Patients who are diagnosed with breast cancer 15.Patients who have a history of stroke and myocardial infarction 16.Patients who are unexplained uterine bleeding 17.Patients who have a history of sensitivity to estrogen compounds

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jondishapour of Medical Science

Street address

University City,Ahvaz

City

Ahvaz

Postal code

15749-61357

Approval date

2011-10-15, 1390/07/23

Ethics committee reference number

ETH-244

Health conditions studied

1

Description of health condition studied

Renal failure

ICD-10 code

N17.9

ICD-10 code description

Acute renal failure, unspecified

Primary outcomes

1

Description

Hemodynamic change

Timepoint

Day of biopsy and next day

Method of measurement

Blood pressure and pulse rate control and orthostatic change

2

Description

Hemoglobin level

Timepoint

One day before biopsy and every 8 time after biopsy for 24 hour

Method of measurement

Hemoglobin level control

3

Description

Hematuria

Timepoint

Day of biopsy and next day

Method of measurement

Urine Analysis

4

Description

Biopsy site hematoma

Timepoint

Day of biopsy and next day

Method of measurement

Ultrasound

5

Description

Bleeding Time

Timepoint

Day of biopsy and next day

Method of measurement

Bleeding Time test with lancet

Secondary outcomes

1

Description

Major bleeding

Timepoint

Day of biopsy and next day

Method of measurement

Hemodynamic change, The need for blood transfusion, Surgery

Intervention groups

1

Description

10 unit cryoprecipitate transfusion on day of biopsy in group 1

Category

Prevention

2

Description

Oral administration of conjugated estrogen 1.25 mg every 8 hours for 5 days before biopsy in Group 2

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital Nephrology ward

Full name of responsible person

kaveh ebadi borna

Street address

Golestan hospital Ahvaz

City

Ahvaz

2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Nephrology Ward

Full name of responsible person

kaveh ebadi borna

Street address

Imam hospital Azadegan Ave. Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Ahvaz University of Medical Science and Health science

Full name of responsible person

Dr. mostafa Feghi

Street address

University City, Ahvaz

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Deputy of Ahvaz University of Medical Science and Health science

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

Ahvaz Jondishapour University of Medical Science and Health Science

Full name of responsible person

Dr. kaveh ebadi borna

Position

Internal Medicine resident

Other areas of specialty/work

Street address

Khanpars. East Elham Street No.9

City

Ahvaz

Postal code

Phone

+98 61 1333 8781

Fax

Email

Ebadiborna.k@ajums.ac.ir ,kavehborna@yahoo.com ,kavehborna@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jondishapour Medical Science and Health Science

Full name of responsible person

Dr. Seyfollah Beladi Musavi

Position

Associate Professor

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

Nephrology Ward, Imam Khomeini Hospital, Ahvaz

City

Ahvaz

Postal code**Phone**

+98 61 1222 7240

Fax**Email**

beladimusavi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz JondiShapour Medical Science and Health Science

Full name of responsible person

Dr. kaveh ebadi borna

Position

Internal Medicine Resident

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

No.9, East Elham Street, Kianpars, Ahvaz

City

Ahvaz

Postal code**Phone**

+98 61 1333 8781

Fax**Email**

ebadiborna.k@ajums.ac.ir ,kavehborna@gmail.com
,kavehborna@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