

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Sub-endometrial injection of vasopressin to control bleeding in postpartum hysterectomy due to abnormally invasive placenta

Protocol summary

Study aim

Evaluation of the effectiveness of sub-endometrial injection of vasopressin for the postpartum bleeding in patients with placental accreta

Design

Two-arm parallel group double blinded randomized trial, phase 3 for 60 patients, randomized by envelopes

Settings and conduct

After providing sufficient explanations and obtaining informed consent in Imam Khomeini hospital complex, Tehran, , the patients' initial data will be collected, and a distinct date for cesarean section will be determined. Participants will then be randomly assigned into intervention or control groups. For patients, ready-to-inject solutions are provided by the hospital pharmacy. The prepared solution for the intervention group is 20 ml in total, containing 1 ml of vasopressin, equivalent to 5 units, which is diluted in 19 ml of 0.9% normal saline. The solution prepared for the control group will also contain 20 ml of 0.9% normal saline. The only person who knows the contents of the solution is the pharmacist, and doctors do not know the contents of the syringes during the operation. After the intervention, the health care personnel will be also blinded.

Participants/Inclusion and exclusion criteria

Pregnant women with more than 18 years of age, with diagnosis of placenta accreta according to ultrasound findings by a radiologist

Intervention groups

For the intervention group, a total of 20 ml, containing 1 ml of vasopressin, equivalent to 5 units, diluted in 19 ml of normal saline 0.9% will be injected. The solution prepared for the control group will also contain 20 ml of 0.9% normal saline.

Main outcome variables

Hemoglobin level before Cesarean Section, Hemoglobin level after Cesarean Section, Blood transfusion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191102045310N1**

Registration date: **2020-04-28, 1399/02/09**

Registration timing: **retrospective**

Last update: **2020-04-28, 1399/02/09**

Update count: **0**

Registration date

2020-04-28, 1399/02/09

Registrant information

Name

fahimeh ghotbizadeh vahdani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2289 9858

Email address

fghotbi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

2017-03-21, 1396/01/01

Actual recruitment end date

2018-03-21, 1397/01/01

Trial completion date

2018-03-21, 1397/01/01

Scientific title

Sub-endometrial injection of vasopressin to control bleeding in postpartum hysterectomy due to abnormally invasive placenta

Public title
Sub-endometrial injection of vasopressin for invasive placenta

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All pregnant women with placenta accreta diagnosed by ultrasound
Exclusion criteria:
History of cardiac diseases History of uncontrolled hypertension History of pelvic pregnancies History of chronic obstructive pulmonary disease

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Type of randomization: simple Randomization unit: individual Randomization tool: envelop Random sequence generation: envelop shuffling Allocation concealment: central randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
After providing sufficient explanations and obtaining informed consent, the patients' initial data will be collected, and a distinct date for cesarean section will be determined. Participants will then be randomly assigned into intervention or control groups. For patients, ready-to-inject solutions are provided by the hospital pharmacy. The prepared solution for the intervention group is 20 ml in total, containing 1 ml of vasopressin, equivalent to 5 units, which is diluted in 19 ml of 0.9% normal saline. The solution prepared for the control group will also contain 20 ml of 0.9% normal saline. The only person who knows the contents of the solution is the pharmacist, and doctors do not know the contents of the syringes during the operation. After the intervention, the health care personnel will be also blinded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Imam Khomeini hospital complex, Baqerkhan St, Chamran, East, Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2017-06-16, 1396/03/26

Ethics committee reference number

IR.TUMS.IKHC.REC.1396.4544

Health conditions studied

1

Description of health condition studied

pregnancy with placenta accreta

ICD-10 code

O00.0

ICD-10 code description

Abdominal pregnancy

Primary outcomes

1

Description

Hemoglobin level decrement

Timepoint

Before and after cesarean section

Method of measurement

Cell Blood Count test done by the hospital laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: a total of 20 ml, containing 1 ml of vasopressin, equivalent to 5 units, diluted in 19 ml of normal saline 0.9% will be injected sub-endometrially.

Category

Treatment - Surgery

2

Description

Control group: The solution prepared for the control group will also contain 20 ml of 0.9% normal saline which will be injected sub-endometrially. .

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Fahimeh Ghotbizadeh Vahdani

Street address

Imam Khomeini hospital complex, Baqerkhan St, Chamran, East, Highway, Tehran

City

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Postal code

1419733141

Phone

+98 21 6119 2613

Email

fghotbi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Imam Khomeini hospital complex, Baqerkhan St, Chamran, East, Highway, Tehran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fahimeh Ghotbizadeh Vahdani

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Imam Khomeini hospital complex, Baqerkhan St, Chamran, East, Highway, Tehran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable