Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 than18 years of age, with diagnosis of placenta accarta 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
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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 randomiation
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
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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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Person responsible for scientific inquiries

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Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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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