Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigation of the effect of uterine cooling during cesarean section on decreasing bleeding during and after delivery in patients undergoing cesarean section

Protocol summary

Study aim
Investigation the effect of uterine cooling during cesarean section in uterine bleeding reduction during and after cesarean and related maternal morbidity

Design
Randomized clinical trial with control and parallel group, single blinded

Settings and conduct
In Kowsar hospital , pregnant women who candidate cesarean delivery and met inclusion criteria divided into 2 group of 150 participants, in intervention group,after delivery of placenta the uterus brought out from abdomen then covered with cold saline soaked sponge in -4 degree centigrade .20 unit oxytosine diluted in ringer lactate infused with rate 1000cc/hr, and uterine incision repaired in 2 layers. In the control group we use dry sponge to cover uterus and 20 unit oxytosine diluted in ringer lactate infused with rate 1000cc/hr, and uterine incision repaired in 2 layers. At the end of surgery the volume of bleed loss calculated by counting the wet gauzes and sponges and the amount of blood in the suction battle and the weight of cesarean pack .

Participants/Inclusion and exclusion criteria
Inclusion criteria: Pregnant women with singleton pregnancy,between 37-40 weeks gestation, application of lower segment incision and spinal anesthesia exclusion criteria: underlying disease such as coagulopathy, abnormal placentation (eg; placenta previa or accereta) , allergy to uterotonic , history of uterine rupture, third c/s or more, uterine rupture during section , preeclampsia and fetal macrosomia

Intervention groups
in intervention group after uterine incision and fetal and placenta extraction, the uterus covered with cold saline soaked sponge in -4 degree centigrade and uterine incision repaired simultaneously. in control group dry gauze was used.

Main outcome variables
Volume of blood during operation; Hemoglobin before operation; Hemoglobin 24 hour afte operation; blood transfusion; hysterectomy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120104008611N11**
Registration date: **2020-06-26, 1399/04/06**
Registration timing: **retrospective**

Last update: **2020-06-26, 1399/04/06**
Update count: **0**

Registration date
2020-06-26, 1399/04/06

Registrant information

Name
Hamideh Pakniat
Name of organization / entity
Qazvin University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 282242452
Email address
hpakniat@qums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-22, 1398/03/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation of the effect of uterine cooling during cesarean section on decreasing bleeding during and after delivery in patients undergoing cesarean section

Public title
Investigation of uterine cooling on reducing of bleeding during and after cesarean section
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Gestational age 37-40 Singletone pregnancy Lower segmant incision cesarean Spinal anesthesia
Exclusion criteria:
Underlying disease(cardiac,liver,renal,polmunary) Allergy to misoprostole and oxytosine Coagolopathy Abnormal placenta(abruption,previa..) Risk factor for post partum hemorrhage like polygestation,macrosomia,polyhydramnious More than 2 prior cesarean History of uterine rupture Complications during surgery including Uterine extension Preeclampsia
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **300**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible participants were randomized by computer generated block of four into two groups; the uterine cooling group and the routine cesarean section group. The random numbers were put into sequentially sealed opaque envelopes
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, women undergoing cesarean section were not informed whether they had undergone uterine cooling intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences
Street address
Vice-Chancellor for Research of Qazvin University of Medical Sciences, Valiasr street, Qazvin
City
Qazvin
Province
Qazvin
Postal code
341513176
Approval date
2019-05-13, 1398/02/23
Ethics committee reference number
IR.QUMS.REC.1398.032

Health conditions studied

1

Description of health condition studied
Post partum hemorrhage
ICD-10 code
072.1
ICD-10 code description
Other immediate postpartum haemorrhage

Primary outcomes

1

Description
Bleeding volume
Timepoint
After placental delivery
Method of measurement
Consumed gauze and sponges and suctioned blood volume and the weight of cesarean pack

2

Description
Hemoglobin concentration after surgery
Timepoint
24 hour after surgery
Method of measurement
Laboratory

Secondary outcomes

1

Description
Patient hemoglobin concentration changes
Timepoint
Before and 24 hour after c/s
Method of measurement
laboratory data

Intervention groups

1

Description
Intervention group: using a cold saline soaked sponge in -4 degree centigrade during repair of uterine incision
Category
Prevention

2

Description
Control group:Infusion of 20 units diluted oxytosin, uterine cavity courage with 2 gauze, repair of uterine incision in 2 layers.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Operating room of Kowsar hospital, qazvin
Full name of responsible person
Vahideh Pand Amuz
Street address
Taleghani Blvd
City
Qazvin
Province
Qazvin
Postal code
34156-13176
Phone
+98 28 3323 6374
Email
v_pandamooz@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Amir Peymani
Street address
Vice-Chancellor for Research of Qazvin University of Medical Sciences, Valiasr street,
City
Qazvin
Province
Qazvin
Postal code
3419915315
Phone
+98 28 3333 6001
Email
research.dpt@qums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Vahideh Pand Amuz
Position
Resident of obstetrics and gynecology
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Taleghani Blvd, Valiasr
City
Qazvin
Province
Qazvin
Postal code
34156-13176
Phone
33236374
Email
v_pandamuz@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person

Dr Hamideh Pakniat

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Taleghani Blvd, Valiasr

City
Qazvin

Province
Qazvin

Postal code
341561`3176

Phone
33236374

Email
hpakniat@qums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Vahideh Pand Amuz

Position
Resident of Obstetric and Gynecology

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Taleghani Blvd

City
Qazvin

Province
Qazvin

Postal code
34156-13176

Phone
33236374

Email
v_pandamuz@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Because sharing participants' personal information is not a goal of our study.

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

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
After obtaining informed consent, patient information was recorded in the questionnaires and after operation, the results were again recorded in the questionnaire for statistical analysis. data sharing will occur after the end of the study.

When the data will become available and for how long
Starting 1 years after publication

To whom data/document is available
Only available for people working in academic institutions

Under which criteria data/document could be used
The results will be available after statistical analysis performed by Statistics Consultant.

From where data/document is obtainable
Applicants should contact Dr Hamideh Paknat, the project manager, to obtain the required documentation or data. Ways of communicating are by email, by phone, or by visiting the Kowsar Qazvin Training Center. Postal address: Kowsar Hospital, Taleghani Street, Qazvin Emal: ipakniat110@yahoo.com Phone no: 028- 33236378

What processes are involved for a request to access data/document
The applicant must first notify the project manager by email.Then, as soon as possible, in less than a week, the Designer will provide the requested information at the discretion.

Comments