

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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 segment incision cesarean Spinal anesthesia

Exclusion criteria:

Underlying disease(cardiac,liver,renal,polmonary) 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 sizeTarget 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

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Province

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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 oxytocin, uterine cavity curette 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Hamideh Pakniat

Position

Assistant Professor

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Specialist

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Person responsible for updating data

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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 Pakniat, 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 Email: 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