Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation and comparison of administrated oxytocin dose based on “rule of threes” algorithm with Williams guideline in the elective cesarean delivery

Protocol summary

Study aim

The aim of this study was to investigate the comparison efficacy of “rule of threes” algorithm with Williams’s guideline in uterine tone evaluations as well as side effects of each approach in the women undergoing to elective cesarean delivery.

Design

In this triple blind study a total of 110 candidate patients for elective cesarean delivery were randomly divided into two groups. The surgeon, analyzer and the person who administrated drug were blind for groups.

Settings and conduct

Background: 110 patients undergoing elective cesarean section Location: Imam Hossein Hospital (2016- 2016) Methods: This prospective, triple-blind, prospective study was performed on 55 patients with ASA I II and undergoing cesarean section. Patients were randomly divided into two groups according to the oxytocin method. Grouping: Group 1 received oxytocin by the Rule of Threes method and group two received oxytocin based on the Williams line. Oxytocin consumption and hemodynamic parameters were recorded and compared in both groups. Conclusion: In both methods there were no abnormal changes in hemodynamics and other complications associated with high doses of oxytocin. Blindness: Three Blind Strains (Patient-Researcher-Data Controller Team)

Participants/Inclusion and exclusion criteria

Inclusion criteria: American Society of Anesthesiologists (ASA) physical status, first to third candidate elective Cesarean delivery Exclusion criteria: labor pain, presence of fetal risk factors for atony, presence of maternal risk factor for atony, diabetes melitus, uterine fibroma, thrombocytopenia< 100000/microliter

Intervention groups

group 1 was received oxytocin using Rule of Threes approach. group 2 was received oxytocin using William’s guideline.

Main outcome variables

The mean level of oxytocin dose in both groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120430009593N13**
Registration date: **2020-03-09, 1398/12/19**
Registration timing: **retrospective**

Last update: **2020-03-09, 1398/12/19**
Update count: **0**

Registration date

2020-03-09, 1398/12/19

Registrant information

Name
Elham Memary

Name of organization / entity
Shahid Beheshti University

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

2016-09-22, 1395/07/01

Actual recruitment end date

2018-11-06, 1397/08/15

Trial completion date

2018-11-06, 1397/08/15

Scientific title

Evaluation and comparison of administrated oxytocin dose based on “rule of threes” algorithm with Williams guideline in the elective cesarean delivery

Public title

Determination of oxytocin dose based on “rule of threes” algorithm and Williams guideline in the elective cesarean delivery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The women who undergoing to the first to third elective Cesarean delivery with spinal anesthetic technique American Society of Anesthesiologists (ASA) physical status I–II

Exclusion criteria:

Labor pain The presence of maternal risk factors for uterine atony The presence of fetal risk factors for uterine atony Diabetes melitus Thrombocytopenia<100000 per microliter Uterine fibroma

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size

Target sample size: **110**

Actual sample size reached: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

• Randomization method: Simple randomization • Randomization Unit: based on patient • Randomization Tool: Random Number Table - block stratified randomization software wnidow version 6.0 Using this software, a random number table is created and the sample list is divided into two groups of 30 each.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants enter two treatment groups based on a random number table. There is also a ready-made package available to the physician and nurse, including 55 packages of the first and 55 packages of the second drug. The data monitoring committee was also blinded of the grouping

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethical commite of Shahid Beheshti Medical University

Street address

Shahid Beheshti University of Medical Sciences, Shahid Erabi St, Ebne Yaman St, Shahid Chamran Highway, Tehran, Iran

City

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Province

Tehran

Postal code

1985717443

Approval date

2018-07-10, 1397/04/19

Ethics committee reference number

IR.SBMU.MSP.REC.1397.462

Health conditions studied

1

Description of health condition studied

Elective cesarean delivery

ICD-10 code

O82

ICD-10 code description

Encounter for cesarean delivery without indication

Primary outcomes

1

Description

creating of adequate uterine tonicity

Timepoint

at 3, 6, 9, 12, and 15 min after onset of surgery

Method of measurement

Uterine tonicity was evaluated as atonic, partial tonicity, adequate tonicity, well contracted and very well contracted by obstetrician.

Secondary outcomes

1

Description

The time of administrated oxytocin to obtain adequate tonicity

Timepoint

At 3, 6, 9, 12, and 15 minute after onset of cesarean

Method of measurement

The mean administrated oxytocin

Intervention groups

1

Description

Intervention group:The patients in “rule of threes” algorithm group received Bolus oxytocin 3IU/3ml (0.9% saline) . At 3 and 6 min, an “inadequate” uterine tone assessment resulted in repeated bolus administration of oxytocin . At 9 min, an “inadequate” uterine tone assessment resulted in intramuscular injection of methylergonovine (0.2 mg /ml). At 15 min, inadequate uterine tone assessment resulted in administration of misoprostol 600 µg buccaly.

Category

Treatment - Drugs

2

Description

Intervention group: The William`s group received Bolus oxytocin 3 ml 0.09 % saline and then oxytocin infusion by pump at 15 ml/min until adequate uterine tonocity achieved then followed by 1-2 ml/min until patient entrance to recovery. At delivery, 3, 6, 9, 12, and 15 min postpartum, the patients were asked if they had flushing, nausea, chest pain, headache, ECG changes such as ST-T wave changes and other complaints. To nausea prophylaxis, all patients received ondansetron 4 mg intravenously after the delivery. Total administrated oxcytocin for both groups was finally recorded and then compared.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان امام حسین

Full name of responsible person

الهام معماری

Street address

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Elham Memari

Position

Associated Professor

Latest degree

Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Some of data can be shared.
When the data will become available and for how long
Get 6 months after publishing
To whom data/document is available
محققین دانشگاهی و کلینیسن ها
Under which criteria data/document could be used
For more research
From where data/document is obtainable
Via email: y.ghorbani.m@gmail.com
What processes are involved for a request to access data/document
After publication
Comments