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Effectiveness of remimazolam on preventing adverse reactions caused by carboprost tromethamine during cesarean section

Submission date
17/09/2023

Recruitment status
No longer recruiting

Registration date
16/11/2023

Overall study status
Completed

Last Edited
14/11/2023

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to evaluate the effectiveness of intravenous administration of remimazolam in preventing adverse reactions triggered by carboprost tromethamine during cesarean section procedures performed under combined spinal and epidural anesthesia (CSEA), thereby improving sedative effects. This approach holds promising potential for widespread application.

Who can participate?
Parturients aged between 24-45 years old scheduled for cesarean sections at risk of postpartum hemorrhage at The third hospital of Baogang Group, China

What does the study involve?
The participants will be assigned via random number table method to either a study group or a control group, resulting in 100 cases in each. All parturients will receive CSEA during cesarean section, followed by administration of carboprost tromethamine (250μg) for preventing postpartum hemorrhage after childbirth. CSEA is performed with 1.8-2 mL of 0.5% bupivacaine and 7-10 mL of 2% lidocaine. The study group will be given remimazolam via intravenous infusion at a rate of 0.3 mg/kg/hr commencing one minute prior to CSEA and concluding with a final dosage adjustment 20 minutes preceding the end of surgery, while the control group will be given the same volume of saline within this time frame. Primary outcome measures were adverse reactions and sedative effects of the parturients.

What are the possible benefits and risks of participating?
Benefits and risks not provided at time of registration.

Where is the study run from?
The Third Hospital of the Baogang Group (China)

When is the study starting and how long is it expected to run for?
October 2022 to September 2023

Who is funding the study?
The Baotou Science and Technology Bureau (China)

Who is the main contact?
Dr Jianjun Fan, fanjianjun2065@163.com (China)

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Effectiveness of remimazolam on preventing adverse reactions caused by carboprost tromethamine during cesarean section

Study objectives
Intravenous administration of remimazolam effectively prevents adverse reactions induced by carboprost tromethamine during cesarean section performed under CSEA, thereby improving sedative effects.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/12/2022, Ethics Committee of The third hospital of the Baogang Group (Qingnian Road, Kunqu District, Baotou City, Inner Mongolia, 014010, China; +86-0472-2166970; bangongshi@cohf.cn), ref: 2022.02/22-28

Study design
Single-center single-blind randomized controlled trial

Primary study design

Interventional

Study type(s)
Safety

Health condition(s) or problem(s) studied
Cesarean section women at risk of postpartum hemorrhage

Interventions
The participants will be assigned via random number table method to either a study group or a control group. All parturients will receive combined spinal and epidural anesthesia (CSEA) during cesarean section, followed by administration of carboprost tromethamine (250μg) for preventing postpartum hemorrhage after childbirth. Combined spinal and epidural anesthesia will be performed with 1.8-2 mL of 0.5% bupivacaine and 7-10 mL of 2% lidocaine. The study group will be given remimazolam via intravenous infusion at a rate of 0.3 mg/kg/hr commencing one minute prior to CSEA and concluding with a final dosage adjustment 20 minutes preceding the end of surgery, while the control group will be given the same volume of saline within this time frame. Primary outcome measures were adverse reactions and sedative effects of the parturients.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Postpartum bleeding volume measured using patient records. The bleeding volume of parturients at 2 hours and 24 hours postpartum and the time to cessation of bleeding are recorded and compared between the two groups.
2. Sedation effect measured using the Ramsay Sedation Scale (RSS) to assess intraoperative sedation levels. The scale is as follows: 1 point: Anxious, restless; 2 points: Awake, calm, cooperative; 3 points: Drowsy, responsive to commands; 4 points: Light sleep, easily awakened; 5 points: Asleep, sluggish response to stimulation; 6 points: Deep sleep, no response to stimulation. Sedation levels were categorized as follows: 1 point indicated inadequate sedation, 2-4 points indicated moderate sedation, and 5-6 points indicated excessive sedation. Sedation efficacy (%) = (Sum of cases with 3-4 points) / Total cases × 100%.
3. Adverse reactions: Adverse reactions (nausea and vomiting, stomach pain, chest pain, palpitations, elevated blood pressure, headache) occurring between admission and the end of surgery. The severity of nausea and vomiting is graded as follows: Level 0: No nausea or vomiting; Grade 1: nausea but no vomiting; Grade 2: Nausea or vomiting 1-2 times within an hour; Level 3: Nausea or vomiting three or more times within an hour

Key secondary outcome(s))
Satisfaction score measured using a patient questionnaire of the satisfaction of the whole treatment process, which is divided into very satisfied, satisfied and dissatisfied, before discharge

Completion date
30/09/2023

Eligibility

Key inclusion criteria
1. Aged 24-45 years old
2. Indication for cesarean section, planned elective cesarean section
3. American Society of Anesthesiologists (ASA) grade I-II
4. Presence of risk factors for uterine atony, such as scar pregnancy, multiple pregnancies, macrosomia, psychological stress, and making natural labor inappropriate.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
24 years

Upper age limit
45 years

Sex
Female

Total final enrolment
100

Key exclusion criteria
1. Genital tract anomalies
2. Coagulation disorders
3. Allergy to drugs and related solvents intended for use during surgery
4. Pre-existing conditions such as severe gastric ulcers, duodenal ulcers, reflux esophagitis, or other conditions that could lead to symptoms such as nausea, vomiting, chest discomfort, palpitations, abdominal pain, or diarrhea

Date of first enrolment
01/10/2022

Date of final enrolment
31/07/2023

Locations

Countries of recruitment
China

Study participating centre

The third hospital of Baogang Group
15, Qingnian Road,Kunqu District
Baotou City
China
014010

Sponsor information

Organisation
Baotou Science and Technology Bureau ()

Funder(s)

Funder type
Government

Funder Name
Baotou Science and Technology Bureau

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the corresponding author Dr Jianjun Fan, fanjianjun2065@163.com (China)

IPD sharing plan summary
Other