

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Clinical evaluation the effect of Xylapi ointment and lidocaine spray on the patient's satisfaction, stress, cooperation and pain level in spinal anesthesia for cesarean section and comparing it with the control group

#### Protocol summary

##### Study aim

Raise awareness about reducing pain and increasing maternal satisfaction when using Xylapi ointment compared to Lidocaine spray in Cesarean Section of pregnant mothers.

##### Design

A parallel-group, single-blind, randomized controlled clinical trial involving 258 patients. They are placed in 3 groups in the form of block randomization and quadruple block.

##### Settings and conduct

This study will be conducted in Bharlo hospital in order to compare the level of cooperation, satisfaction, pain and anxiety of pregnant mothers over 37 weeks and candidates for caesarean section. In this study, one-way blinding was done for the patients and the patients were placed in three groups of 86 people, in the intervention group 1 of 10 grams of Xylapi ointment at the needle entry site and in the intervention group 2 of 3 puffs of 10% lidocaine spray at the entry site. A needle is used to create anesthesia, and in the control group, 3 puffs of distilled water are used, and the results will be compared between the 3 groups based on the visual pain scale and scoring by the anesthesiologist with the cooperation of the mothers.

##### Participants/Inclusion and exclusion criteria

Entry criteria: Pregnant women with a gestational age of over 37 weeks who are candidates for elective cesarean section. Exclusion criteria: gestational age below 37 weeks : candidates for emergency cesarean section : chronic diseases of blood pressure and diabetes : allergy to lidocaine : addiction : contraindications for spinal anesthesia.

##### Intervention groups

In intervention group 1, 10 grams of Xylapi ointment is used at the needle entry site, and in intervention group 2, 3 puffs of 10% lidocaine spray are used at the needle

entry site to create anesthesia. 3 puffs of distilled water are also used in the control group.

##### Main outcome variables

Mother's Pain : Satisfaction : Anxiety : Cooperation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230128057251N1**

Registration date: **2023-05-29, 1402/03/08**

Registration timing: **prospective**

Last update: **2023-05-29, 1402/03/08**

Update count: **0**

##### Registration date

2023-05-29, 1402/03/08

##### Registrant information

##### Name

amirabbas motezaker

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4427 4096

##### Email address

amir.mt1999@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-22, 1402/04/01

##### Expected recruitment end date

2024-06-21, 1403/04/01

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Clinical evaluation the effect of Xylapi ointment and lidocaine spray on the patient's satisfaction, stress, cooperation and pain level in spinal anesthesia for cesarean section and comparing it with the control group

**Public title**  
Clinical evaluation the effect of Xylapi ointment and lidocaine spray on the patient's satisfaction, stress, cooperation and pain level in spinal anesthesia for cesarean section and comparing it with the control group

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Pregnant women referred to Bharlo Hospital with a gestational age of more than 37 weeks who are candidates for elective cesarean section  
**Exclusion criteria:**  
Gestational age below 37 weeks Pregnant women who are candidates for emergency cesarean section Pregnant women with chronic hypertension and diabetes History of allergy to lidocaine History of addiction and contraindications for spinal anesthesia

**Age**  
From **15 years** old to **50 years** old

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: **258**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
We divide the patients into 3 groups by block randomization and quadruple block, totaling 86 people, which include 258 people and have a gestational age of more than 37 weeks. In the intervention group 1, which consists of 86 people, 10 grams of Xylapi ointment is used in a cross-sectional area of 10 square centimeters (according to the anesthesiologist's opinion) 20 to 30 minutes before the spinal injection in the place where the needle is inserted to create anesthesia. In the intervention group 2 as well 3 puffs of 10% lidocaine spray are used at the needle insertion site 5-10 minutes before the spinal. In the control group, 3 puffs of distilled water are used 10 minutes before the spinal.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
In this study, the subjects are aware that a new method is being studied and researched, but they are blinded to

which group they belong to and which drug is being studied on them.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees Of School Of Medicine  
Tehran University of Medical Sciences

##### Street address

Research and Technology Affairs Management Unit,  
Room 604, 6th Floor, Headquarters of Tehran  
University of Medical Sciences, Corner of Qods St,  
Keshavarz Blvd

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

#### Approval date

2023-01-23, 1401/11/03

#### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.702

## Health conditions studied

### 1

#### Description of health condition studied

caesarean section

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

The amount of mother's pain during spinal needle insertion

#### Timepoint

After caesarean section

#### Method of measurement

Visual Analog Scale

### 2

#### Description

The level of mother's satisfaction during transfer to the ward (end of recovery)

### **Timepoint**

After caesarean section

### **Method of measurement**

Visual Analog Scale

### **3**

#### **Description**

The level of mother's anxiety before the insertion of the spinal needle

#### **Timepoint**

After caesarean section

#### **Method of measurement**

Visual Analog Scale

### **4**

#### **Description**

The level of cooperation of the mother according to the anesthesiologist

#### **Timepoint**

After caesarean section

#### **Method of measurement**

Anesthesiologist grading from 1 to 10

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

In the intervention group 1, which consists of 86 people, 10 grams of Xylapi ointment is used in a cross-sectional area of 10 square centimeters (according to the opinion of an anesthesiologist) 20 to 30 minutes before the spinal injection at the place where the needle is inserted to create anesthesia. Then it is patched. The preb and lid are done and the mother is put under spinal anesthesia with a G25 needle and half percent marcaine ampoule.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

In intervention group 2, 3 puffs of 10% lidocaine spray are used at the needle insertion site 5-10 minutes before the spinal injection.

#### **Category**

Treatment - Drugs

### **3**

#### **Description**

In the control group, 3 puffs of distilled water are used 10 minutes before spinal.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Baharlou hospital

##### **Full name of responsible person**

Zahra Ghale Noii

##### **Street address**

Behdari St., Rah Ahan Sq.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1339973111

##### **Phone**

+98 21 5565 8500

##### **Email**

baharloo@sina.tums.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Zahra Ghale Noei

##### **Street address**

Pour Sina St., District 6, Tehran Province

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1417653761

##### **Phone**

+98 21 8889 6696

##### **Email**

tumspr@tums.ac.ir

#### **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**

Zahra Ghale Noie

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Behdari St., Rah Ahan Sq.

**City**

Tehran

**Province**

Tehran

**Postal code**

1339973111

**Phone**

+98 21 5565 8500

**Email**

zgh.5068@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Zahra Ghale Noie

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Behdari St., Rah Ahan Sq.

**City**

Tehran

**Province**

Tehran

**Postal code**

1339973111

**Phone**

+98 21 5565 8500

**Email**

zgh.5068@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Zahra Ghale Noie

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Behdari St., Rah Ahan Sq.

**City**

Tehran

**Province**

Tehran

**Postal code**

1339973111

**Phone**

+98 21 5565 8500

**Email**

zgh.5068@gmail.com

## 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**

This study aims to compare the effect of Xylapi ointment with lidocaine spray on reducing pain and anxiety during spinal surgery for cesarean section, and after collecting all the information related to the topics under study, it will be given to the researchers.

**When the data will become available and for how long**

After completing the data collection and writing the thesis in 1403

**To whom data/document is available**

Specialists in obstetrics and gynecology and anesthesia

**Under which criteria data/document could be used**

Persons who have access to the information by writing a letter to the research unit of Tehran University of Medical Sciences and the holder of the code of ethics and the IRCT code by referring to the research assistant of Baharlu Hospital.

**From where data/document is obtainable**

Research Unit of Tehran University of Medical Sciences, Research Vice-Chancellor of Baharlu Hospital

**What processes are involved for a request to access data/document**

Writing a letter with the research unit of Tehran University of Medical Sciences and receiving the code of ethics and referring to the research unit of Baharlu Hospital and receiving information

**Comments**