

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparison the analgesic effects of intravenous acetaminophen , intramuscular tramadol and suppository diclofenac in the treatment of cesarean pain

#### Protocol summary

##### Summary

In this study, intravenous pain relief and side effects of three drugs, acetaminophen, diclofenac suppository and intramuscular injection of tramadol are determined and compared. Study on 105 pregnant women over 34 weeks for elective cesarean section at Al Zahra Hospital, Tabriz Vtalgany have been done and are willing to participate in the study. The patients are taking pain medications before surgery or have a history of mental problems and anxiety are excluded. Patients were randomly divided into three equal groups of 35 persons . After entering the patient's medical department is aware of the three groups of patients, the drug. For the first group, rectal suppositories diclofenac 100 mg every 8 hours (made in Iran, drug manufacturing company) For the second group IV Acetaminophen 1g/100ml infusions every 6 hours 15 minutes (making Iran Couble drugs) And for third group , Tramadol 50mg intramuscular injection every 8 hours (made in Iran, drug manufacturing companies). Pain will be measured every 2, 6 and 24 hours after surgery with Visual assay of pain (VAS) by scaled ruler (0 to 10). This is a double blind study. Pain is considered as the primary outcome.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201301235448N3**  
Registration date: **2013-04-10, 1392/01/21**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-04-10, 1392/01/21

#### Registrant information

##### Name

Fateme Mallah

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41133336360

##### Email address

mallahf@tbzmed.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

vice chancellor of research, Tabriz University of Medical Sciences

#### Expected recruitment start date

2013-01-29, 1391/11/10

#### Expected recruitment end date

2013-12-31, 1392/10/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison the analgesic effects of intravenous acetaminophen , intramuscular tramadol and suppository diclofenac in the treatment of cesarean pain

#### Public title

Comparison the analgesic effects of intravenous acetaminophen , intramuscular tramadol and suppository diclofenac in the treatment of cesarean pain

#### Purpose

Treatment

## **Inclusion/Exclusion criteria**

Inclusion criteria: 1 - Pregnant women who are candidates for elective or emergency cesarean section to link to the list of operating room training center - Al Zahra Hospital, Tabriz and taleghany hospital have been. 2 - pregnant women over 34 weeks 3 - patient willingness to participate in the study exclusion criteria of study: 1 - Patients who have any reason to take any pain medications before surgery. 2 - Have the contra indications for NSAID or paracetamol or tramadol prescription, such as peptic ulcer, coagulopathy, renal failure, liver failure, asthma, and allergy medicines .... 3 - a history of mental problems and anxiety

### **Age**

No age limit

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

No information

### **Sample size**

Target sample size: **105**

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

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Tabriz university institutional ethics review board

##### **Street address**

Third Floor, Central Building of Number2, Golgasht Street

##### **City**

Tabriz

##### **Postal code**

#### **Approval date**

2012-02-20, 1390/12/01

#### **Ethics committee reference number**

5/4/9921

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

infertility

#### **ICD-10 code**

N97

#### **ICD-10 code description**

Female Infertility

## **Primary outcomes**

### **1**

#### **Description**

Pain Relief

#### **Timepoint**

Pain of 2 hours, 6 hours and 24 hours after surgery is measured

#### **Method of measurement**

Visual assay of pain (VAS) by scaled ruler (0 to 10) is zero, no pain and 10 the worst pain at the show, be assesse

## **Secondary outcomes**

### **1**

#### **Description**

Improve mobility

#### **Timepoint**

Up to 8 hours after surgery

#### **Method of measurement**

Questionnaire

### **2**

#### **Description**

reduce the risk of postoperative thromboembolic disease

#### **Timepoint**

After Surgery

#### **Method of measurement**

Questionnaire

### **3**

#### **Description**

Improve the ability of the mother to child care and breastfeeding

#### **Timepoint**

After Surgery

#### **Method of measurement**

Questionnaire

### **4**

#### **Description**

Shorten the period of hospitalization

#### **Timepoint**

After Surgery

#### **Method of measurement**

Questionnaire

## 5

### **Description**

Reduce hospital costs And increase patient satisfaction

### **Timepoint**

After Surgery

### **Method of measurement**

Questionnaire

## **Intervention groups**

### 1

### **Description**

Group1 versus rectal diclofenac 100 mg every 8 hours (made in Iran, drug manufacturing company)

### **Category**

Treatment - Drugs

### 2

### **Description**

In group2: IV Acetaminophen 1g/100ml infusion for 15 minutes every 6 hours in patients over 50 kg. In patients under 50 kg, 15 mg / kg every 6 hours (making Iran Couble medicine)

### **Category**

Treatment - Drugs

### 3

### **Description**

In group3: muscle tramadol 50mg injections every 8 hours (made in Iran, drug manufacturing company) will be used

### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

### **Recruitment center**

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

Alzahra Hospital, Taleghani Hospital

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

#### **Street address**

#### **City**

Tabriz

## **Sponsors / Funding sources**

### 1

### **Sponsor**

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

Tabriz University of Medical Sciences

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

vice chancellor of research

#### **Street address**

Tabriz university of medical sciences, Golgasht street, Azadi avenue

### **City**

Tabriz

### **Grant name**

### **Grant code / Reference number**

### **Is the source of funding the same sponsor organization/entity?**

Yes

### **Title of funding source**

Tabriz University of Medical Sciences

### **Proportion provided by this source**

100

### **Public or private sector**

empty

### **Domestic or foreign origin**

empty

### **Category of foreign source of funding**

empty

### **Country of origin**

### **Type of organization providing the funding**

empty

## **Person responsible for general inquiries**

### **Contact**

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

Tabriz University of Medical Sciences

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

D.Fatemeh Mallah

#### **Position**

associate professor

#### **Other areas of specialty/work**

#### **Street address**

Alzahra Hospital, bagh-shomal, Arteshe Jonoubi street

#### **City**

Tabriz

#### **Postal code**

#### **Phone**

+98 41 1553 9161

#### **Fax**

#### **Email**

wrhrcenter@gmail.com

#### **Web page address**

## **Person responsible for scientific inquiries**

### **Contact**

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

Tabriz University of Medical Sciences

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

Dr.Fatemeh Mallah

#### **Position**

gynecologist

#### **Other areas of specialty/work**

#### **Street address**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

Dr.Fatemeh Mallah

**Position**

Assistent professor

**Other areas of specialty/work****Street address**

Taleghani Hospital Rah Ahan Sq

**City**

Tabriz

**Postal code****Phone**

+98 41 1556 6449

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*