

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Clinical Trial "Assessment of the effect of Diclofenac gel and EMLA ointment on vein puncture pain severity with vein catheter in patient undergoing cesarean section"

#### Protocol summary

##### Summary

Introduction and background: Pain and its control is one of the health problems in the world. Vein Puncture is one of the most usual invasive procedures performed by nurses. So finding methods to decrease the pain caused by vein puncture is very important. Objectives: The present study was planned to evaluate the efficacy of applying Diclofenac gel and EMLA (Eutectic mixture of local anesthetics) ointment on vein puncture pain severity with vein catheter in the patients undergoing cesarean section. Design, Setting and conduct: This is a randomized, single blind, placebo controlled clinical trial that was conducted on 90 women undergoing cesarean section in Imam Ali Hospital's maternity section in Amol city. Between 9th of April 2010 and 10th of June 2010 eligible patients were randomly divided into EMLA group (E group), Diclofenac group (D group) or Placebo group (P group) in equal numbers. Study Entry Requirements: aged 18 to 40 years; don't have any defect in terms of mental and visual and verbal ability; Patients who doesn't have any sensitivity to local anaesthetics or allergy to NSAIDs; haven't used analgesics during the previous 24 hours; don't have Favism, methemoglobin, liver and kidney disease, asthma, skin allergies, skin dermatitis, wound in the area assigned for intervention, active gastrointestinal bleeding, allergies to topical anaesthetics and non steroidal anti-inflammatory drugs included in this study. Study Exclusion: if the insertion vein catheter be unsuccessful in the first attempt or the caesarean section become an emergency operation. Interventions: for the Patients in D Group used diclofenac gel, E Group used EMLA ointment and P Group used Vaseline ointment in the area of the catheter insertion one hour before catheter insertion. Main outcome measures: The severity was pain. Background variables: age, history of the installation of vein catheter, having therapeutic support systems, level of monthly income

and the level of the patient's education.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201008234618N1**

Registration date: **2010-09-09, 1389/06/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-09-09, 1389/06/18

##### Registrant information

##### Name

Sediqeh Khalili

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1214 4000

##### Email address

khalili@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2010-04-09, 1389/01/20

##### Expected recruitment end date

2010-06-10, 1389/03/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Clinical Trial "Assessment of the effect of Diclofenac gel and EMLA ointment on vein puncture pain severity with vein catheter in patient undergoing cesarean section"

**Public title**  
Clinical Trial "Assessment of the effect of Diclofenac gel and EMLA" ointment"

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
Study Entry Requirements: aged 18 to 40 years; don't have any defect in terms of mental and visual and verbal ability; Patients who doesn't have any sensitivity to local anaesthetics or allergy to NSAIDs; haven't used analgesics during the previous 24 hours; don't have Favism, methemoglobin, liver and kidney disease, asthma, skin allergies, skin dermatitis, wound in the area assigned for intervention, active gastrointestinal bleeding, allergies to topical anaesthetics and non steroidal anti-inflammatory drugs included in this study. Study Exclusion: if the insertion vein catheter be unsuccessful in the first attempt or the caesarean section become an emergency operation.

**Age**  
From **18 years** old to **40 years** old

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **90**

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

**Randomization description**

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

**Blinding description**

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**  
**Name of ethics committee**  
Islamic Azad University, Medical Sciences Tehran  
**Street address**

Shariaty, Zargande  
**City**  
Tehran  
**Postal code**  
19168  
**Approval date**  
2010-04-29, 1389/02/09  
**Ethics committee reference number**  
2927

## Health conditions studied

### 1

**Description of health condition studied**  
Diclofenac gel on vein puncture pain severity with vein catheter  
**ICD-10 code**  
Y45.3  
**ICD-10 code description**  
Other nonsteroidal anti-inflammatory drugs

### 2

**Description of health condition studied**  
EMLA ointment on vein puncture pain severity with vein catheter  
**ICD-10 code**  
Y48.3  
**ICD-10 code description**  
Local anaesthetics

## Primary outcomes

### 1

**Description**  
vein puncture pain severity with vein catheter  
**Timepoint**  
3-5 minutes after vein catheter installation  
**Method of measurement**  
Visual analogue scale

## Secondary outcomes

### 1

**Description**  
Short-term effects of topical drugs diclofenac gel, anesthetic cream EMLA and vaseline cream  
**Timepoint**  
application local medications later One hour  
**Method of measurement**  
Checklist of short-term effects of topical drugs

## Intervention groups

### 1

**Description**  
Researcher put the size of 2 g of EMLA ointment (EMLA

ointment 5% mixture of lidocaine 2.5% and 2.5% prilocaine Manufactured by Tehran Chemie Pharmaceutical Co. Tehran - Iran, that containing 30 - gram tubes with confirmation Ministry of Health) in the level of the 2.5 × 4 cm EMLA group ointment on the behind at the left hand, before an hour catheter insertion and covered the area with transparent dressing.

**Category**

Prevention

**2****Description**

Researcher put the size of 100 mg of diclofenac gel (diclofenac gel 1% Each 100 grams contains: diclofenac Diethyl ammonium equivalent to diclofenac sodium 1 g, Manufactured by Behvzan Co. Rasht - Iran that containing 60 grams tubes with confirmation Ministry of Health) in the level of the 1.9 × 3.8 cm diclofenac group gel on the behind at the left hand, before an hour catheter insertion and covered the area with transparent dressing.

**Category**

Prevention

**3****Description**

Researcher put the size of 100 mg of Vaseline ointment (Vaseline ointment compounds that liquid paraffin and glycerin, Lanolin and Fragrance free, Manufactured by Pars Hayan Co. Iran that containing 45 grams tubes with confirmation Ministry of Health) in the level of the 1.9 × 3.8 cm placed group on the behind at the left hand, before an hour catheter insertion and covered the area with transparent dressing.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Ali Hospital

**Full name of responsible person**

Sediqueh Khalili graduate student orientation Surgical Nursing Education

**Street address**

Nour Street

**City**

Amol

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Sediqueh Khalili (personal)

**Full name of responsible person**

Sediqueh Khalili

**Street address**

37, 4th Fajr street, Nour Street

**City**

Amol

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Sediqueh Khalili (personal)

**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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Sediqueh Khalili

**Position**

Nurse / Postgraduate Nursing Student

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

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

Mazandaran University of Medical Sciences

**Full name of responsible person**

Sediqueh Khalili

**Position**

Nurse / Postgraduate Nursing Student

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

Joybar Three-way, Imam Square

**City**

Sari

**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*