Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 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

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Sediqeh Khalili
Name of organization / entity
Mazandaran University of Medical Sciences
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Iran (Islamic Republic of)
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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

Sediqeh Khalili graduate student orientation Surgical Nursing Education

Street address

Nour Street

City

Amol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sediqeh Khalili (personal)

Full name of responsible person

Sediqeh 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

Sediqeh 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

Sediqeh Khalili

Position

Nurse / Postgraduate Nursing Student

Other areas of specialty/work

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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