

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Comparison of EMLA cream with rattles on reducing immunization pain in infants of four months

Protocol summary

Summary

Pain response in infants is higher than adults. Therefore, applying methods of pain control by health team members is essential. Vaccination is one of the most painful events during infancy that often is done without pain management. The purpose of this study is to compare the effect of EMLA cream with rattles on reducing immunization pain in infants of four months. This study is a randomized clinical trial which will be conducted on 50 healthy infants referred to health centers for DTP vaccine in Gonabad, Iran. They will be randomly assigned to three groups as EMLA cream, rattles and control. Control group of infants will be placed in the blankets on the bed to be injected as usual. Researcher will shake rattles from 30 seconds before until 15 seconds after injection of the vaccine for rattles group of infants. For EMLA group, 2 g of EMLA cream will be applied in place of vaccine. After an hour, infant pain questionnaire will be completed before, during and after vaccination of infants.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207153150N3**
Registration date: **2012-09-29, 1391/07/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-09-29, 1391/07/08

Registrant information

Name

Mahdi Basiri Moghadam

Name of organization / entity

Gonabad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 53 3722 3028

Email address

basiri1344@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Gonabad university of medical sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of EMLA cream with rattles on reducing immunization pain in infants of four months

Public title

Comparison of EMLA cream with rattles on reducing immunization pain in infants of four months

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Being awake and calm before vaccination; not suffering from diarrhea and colds during the vaccination; term infants; analgesic drug for 48 hours before vaccination is not received by the mother and infant. Exclusion criteria: mother refusing to continue after applying EMLA cream.

Age

From **4 years** old to **4 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Gonabad univercity of medical sciences

Street address

Vice chancellor for research, Gonabad university of medical sciences, Next to the Asian Road

City

Gonabad

Postal code

9691793718

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

90/7

Health conditions studied

1

Description of health condition studied

The pain of vaccine

ICD-10 code

M79.6

ICD-10 code description

Pain in limb

Primary outcomes

1

Description

pain

Timepoint

Before, during and after injection

Method of measurement

modified behavioral pain scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: routine procedures

Category

N/A

2

Description

EMLA group: In addition to routine procedures, applying 2 g of EMLA cream in place of vaccine

Category

Prevention

3

Description

Rattles group: In addition to routine procedures, Shaking rattles from 30 seconds before until 15 seconds after injection.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center of Gonabad city

Full name of responsible person

Street address

City

Gonabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Gonabad University of Medical Sciences

Full name of responsible person

Ali Ekrami

Street address

Gonabad University of Medical Sciences and Health Services, Next to the Asian Road

City

Gonabad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Mahdi Basiri Moqadam

Position

Master of Science in Nursing Education, Faculty Member

Other areas of specialty/work

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Web page address

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