

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Evaluating application of lidocaine spray vs. Normal saline spray in preventing complications of neonatal intubation

Protocol summary

mousavi-m@medilam.ac.ir

Summary

In this study we want to evaluate effect of application of lidocaine spray vs. Normal saline spray before neonatal intubation on vagus stimulation(blood pressure,heart rate),oxygen saturation and time of intubation. We conducted a randomized, double-blind, placebo-controlled during January 2014 to July 2014,include 60 neonates with gestational age more than30 week and exclude neonates less than 30 weeks then divided in two group. The Control group receive spray normal saline and intervention group receive spray lidocaine prior to intubation and blood pressure,heart rate,oxygen saturation and time was measured befor and after intubation and registered in questionnaires .

Recruitment status

Recruitment complete

Funding source

Ilam University of Medical Sciences

Expected recruitment start date

2014-01-20, 1392/10/30

Expected recruitment end date

2014-07-20, 1393/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305188680N2**

Registration date: **2014-02-03, 1392/11/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-02-03, 1392/11/14

Registrant information

Name

Mirhadi Mussavi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3327 2094

Email address

Scientific title

Evaluating application of lidocaine spray vs. Normal saline spray in preventing complications of neonatal intubation

Public title

Application of lidocaine in neonatal intubation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Neonate with GA more than 30 weeks ;without oropharyngeal anomaly and renal mass ;without congenital heart disease Exclusion criteria :Neonates before 30weeks; neonates with renal mass or oropharyngeal anomaly ;neonates with congenital heart disease

Age

From **1 year** old to **28 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ilam University of Medical Sciences

Street address

Banganjab

City

Ilam

Postal code**Approval date**

2013-12-22, 1392/10/01

Ethics committee reference number

EC/92/h/157

Health conditions studied**1****Description of health condition studied**

local Vagous nerve anesthesia

ICD-10 code

G52.2

ICD-10 code description

Disorders of vagus nerve

Primary outcomes**1****Description**

heart rate

Timepoint

before and after intervention

Method of measurement

monitor bite/min

2**Description**

blood pressure

Timepoint

before and after intervention

Method of measurement

blood pressure monitor mmhg

3**Description**

oxygen saturation

Timepoint

before and after intervention

Method of measurement

pulsoxymeter mmhg

Secondary outcomes**1****Description**

Intubation time

Timepoint

before and after intervention

Method of measurement

cornometer second

Intervention groups**1****Description**

lidocain spray 1puff (3 mg/kg)before intubation

Category

Prevention

2**Description**

Normal saline spray 1 puff before intervention

Category

Prevention

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

NICU , Mustafa Khomeini Hospital, Ilam

Full name of responsible person

Dr.Mussavi,Hadi

Street address

Mustafa Khomeini Hospital, Ilam

City

Ilam

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

drTaheri,Morovat

Street address

Banganjab

City

Ilam

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ilam 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

Ilam University of Medical Sciences

Full name of responsible person

Dr.Mussavi,MirHadi

Position

Assistant professor

Other areas of specialty/work

Street address

Mustafa Khomeini Hospital, Ilam, Iran

City

Ilam

Postal code

Phone

+98 84 1222 7120

Fax

Email

drmussavihadi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Dr.Mussavi,MirHadi

Position

Assistant proffessor

Other areas of specialty/work

Street address

Mustafa Khomeini Hospital, Ilam, Iran

City

Ilam

Postal code

Phone

+98 84 1222 7120

Fax

Email

drmussavihadi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Dr.Mussavi,Mirhadi

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

+98 84 1222 7120

Fax

Email

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