

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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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

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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
fefor and after intervention

Method of measurement
monitor bite/min

2

Description
blood pressure

Timepoint
befor and after intervention

Method of measurement
blood pressure monitor mmhg

3

Description
oxygen saturation

Timepoint
befor and after intervention

Method of measurement
pulsioxymeter mmhg

Secondary outcomes

1

Description
Intubation time

Timepoint
befor and after intervention

Method of measurement
cornometer secound

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
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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