

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effectiveness of oral sucrose and swaddling, on pain of nasogastric tube placement in premature neonates

Protocol summary

Summary

The aim of this cross-over clinical trial comparing the effectiveness of oral sucrose and swaddling, on pain of nasogastric tube placement in premature neonates. This study of 57 cases of samples available in selected medical centers, will do. All babies have qualified researcher after obtaining written informed consent from the parents of three nasal tube placement procedures - gastric by routine methods, will wrap and oral sucrose. And depending on which of the groups were randomly assigned to be defined by the above three methods will be different. In this study, the two cameras to record behavioral responses and physiological responses to pain caused by neonatal nasogastric tube placement will be used. The information gathered will be used Split check list. The first part of the research, including demographic characteristics and infant PIPP tool is the second part, which will be used to assess neonatal pain. Pain check list were interpreted by two experienced nurses and to determine the agreement between the scores of Cohen's Kappa agreement will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201209304617N2**

Registration date: **2012-10-10, 1391/07/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-10-10, 1391/07/19

Registrant information

Name

Mahnaz Jabraeili

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Deputy of research, Tabriz University of Medical Sciences

Expected recruitment start date

2012-10-01, 1391/07/10

Expected recruitment end date

2013-05-31, 1392/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of oral sucrose and swaddling, on pain of nasogastric tube placement in premature neonates

Public title

comparing the effectiveness of oral sucrose and swaddling, on pain in premature neonates

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: orders placed nasogastric tube by a doctor to be written or the indicated substitutions, gestational age infants between 34 to 28 weeks, birth weight more than a kilogram, absence Congenital anomalies in the nasal area, the lack of neurological deficits including seizures, intraventricular hemorrhage

greater than grade 2, and ventricular Leukomalacia, the lack of any indication for surgery, not IUGR, severe medical conditions requiring treatments such as sedatives, muscle relaxants, antiepileptic, or analgesic drugs, Completed parental consent form and not painful procedure an hour before the start of procedure. Exclusion criteria: video quality is not suitable for interpretation, placement of a nasogastric tube if the first is not possible, if the baby does not get to be an effective method of pain.

Age

From **28 years** old to **34 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **57**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Deputy of research, Tabriz University of Medical Sciences

Street address

Deputy of Research, Tabriz University of Medical Sciences ,Golgasht street , Tabriz

City

Tabriz

Postal code

977-5138947

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

5/4/10778

Health conditions studied

1

Description of health condition studied

Reducing pain

ICD-10 code

Z40-54

ICD-10 code description

Persons encountering health services for specific procedures and health care

Primary outcomes

1

Description

Premature Infant Pain Profile (PIPP) Score

Timepoint

Two minute befor, During, Five minute after

Method of measurement

Standard PIPP Score

Secondary outcomes

empty

Intervention groups

1

Description

The first group, swaddling two minutes prior the intervention and the nasogastric tube will be inserted for them and will be monitored from two minutes before intervention until five minutes after intervention.

Category

Prevention

2

Description

The secode grope receiving 0.5 cc oral sucrose two minutes before the intervention and the nasogastric tube will be inserted for them and will be monitored from two minutes before intervention until five minutes after intervention.

Category

Prevention

3

Description

The third group received the routine approach and will be monitored from two minutes before intervention until five minutes after intervention.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Educational Center Affiliated Medical Sciences of Tabriz;Iran

Full name of responsible person

Shamsi Salimi

Street address**City**

Tabriz

2**Recruitment center****Name of recruitment center**

29 Bahman Hospital

Full name of responsible person**Street address**

Rahnamai Street;Tabriz;Iran

City

Tabriz

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Deputy of research, Tabriz University of Medical Sciences

Full name of responsible person

Dr Ostad Rahimi

Street addressResearch Department, Central Building , Golgasht ,
Tabriz Tabriz**City**

Tabriz

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

Yes

Title of funding source

Deputy of research, Tabriz 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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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*