Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Oct 2026

Comparing the effect of swaddle and sucrose combination with unique effect of both swaddle, sucrose or placebo on the control of pain secondary to retinopathy of prematurity examination of premature neonates

Protocol summary

Summary

Objective: The aim of the study was comparing the effect of swaddle and sucrose combination with unique effect of both swaddle, sucrose or placebo (distilled water) on the control of pain secondary to retinopathy of prematurity examination of premature neonates. Design: Randomized, double–blind placebo controlled study. Setting: Single center, in Istanbul, Turkey. Patients: Premature neonates who underwent first retinopathy of prematurity examination. Interventions: Group 1(Placebo group): Neonates who were given distilled water 2 minutes before the procedure (n= 21); group 2: Neonates who were swaddled 15 minutes before the procedure (n= 20); group 3: Neonates who were given 0.6 ml 24% sucrose 2 minutes before the procedure (n= 22); group 4: Neonates who were swaddled 15 minutes before the procedure and who were given 0.6 ml 24% sucrose 2 minutes before the procedure (n= 20). Main outcome measures: Primary outcome measure was the “Premature Infant Pain Profile” (PIPP), which includes assessment of facial expressions, heart rate, oxygen saturation and takes behavioral state and gestational age into consideration. Secondary outcome measures were heart rate differences, desaturation, crying time and the degree of cry.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014122610279N5**
Registration date: **2015-02-24, 1393/12/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-02-24, 1393/12/05

Registrant information

Name

Ozge Serce Pehlevan

Name of organization / entity

Zeynep Kamil Maternity and Children Education and Training Hospital

Country

Turkey

Phone

08 60 193 612 0900

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ozge.serce@marmara.edu.tr

Recruitment status

Recruitment complete

Funding source

None

Expected recruitment start date

2010-12-01, 1389/09/10

Expected recruitment end date

2011-08-31, 1390/06/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of swaddle and sucrose combination with unique effect of both swaddle, sucrose or placebo on the control of pain secondary to retinopathy of prematurity examination of premature neonates

Public title
Swaddle and/or sucrose role in the pain control during eye examination
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria; 1. Premature neonates who underwent first retinopathy of prematurity examination. Exclusion criteria; 1. Invasive or noninvasive mechanical ventilation therapy during retinopathy of prematurity examination. 2. Neonates who take analgesia, sedative medicine. 3. Asphyxia 4. Intraventricular hemorrhage 5. Neonates who were resuscitated 6. Neonates who had congenital anomaly
Age
From **28 days** old to **2 months** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **83**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Factorial
Other design features
Neonates were divided by four group; group 1(Placebo group): Neonates who were given distilled water 2 minutes before the procedure (n= 21); group 2: Neonates who were swaddled 15 minutes before the procedure (n= 20); group 3: Neonates who were given 0.6 ml 24% sucrose 2 minutes before the procedure (n= 22); group 4: Neonates who were swaddled 15 minutes before the procedure and who were given 0.6 ml 24% sucrose 2 minutes before the procedure (n= 20). Neonates were randomly assigned to one of four groups, using a computer generated randomization programme. The packed colorless study solutions were provided by the pharmacy in sealed envelopes to the patient’s nurse 3 minutes before the examination. The nurse, ophthalmologist, and investigators and the parents were blinded to the group assignment. Tropicamide (0.5%) and fenilefrin HCL were dropped to the eyes 2 times (10 minute interval) 60 minutes before eye examination, and local anesthetic medicine (Proparacaine; Alcaine drop 0.5%) were dropped to the eyes 30 minutes before the examination. Each neonate was equipped with an oxisensor connected to a Nelcor pulse oximeter (Ovidien RMS).

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Zeynep Kamil Maternity and Children's Education and Training Hospital Ethical Committee
Street address
No:3-4, Dr. Burhanettin Üstünel Sokak., Zeynep Kamil Mahallesi
City
Istanbul
Postal code
34668
Approval date
2010-12-27, 1389/10/06
Ethics committee reference number
19216

Health conditions studied

1

Description of health condition studied
Retinopathy of prematurity
ICD-10 code
H35-1
ICD-10 code description
Retinopathy of prematurity

Primary outcomes

1

Description
Premature infant pain scale (PIPP)
Timepoint
30th and 60th second, 2nd minute for both eye examination, also 4th minute for right eye examination
Method of measurement
Video records

Secondary outcomes

1

Description
Crying time
Timepoint
30th and 60th second, 2nd minute for both eye examination, also 4th minute for right eye examination
Method of measurement
Video records

2

Description
Desaturation (<85% for 10 seconds)
Timepoint
30th and 60th second, 2nd minute for both eye

examination, also 4th minute for right eye examination

Method of measurement

Video records

3

Description

Frequency of bradycardia (<100 bpm)

Timepoint

30th and 60th second, 2nd minute for both eye examination, also 4th minute for right eye examination

Method of measurement

Video records

4

Description

Frequency of tachycardia (>180 bpm)

Timepoint

30th and 60th second, 2nd minute for both eye examination, also 4th minute for right eye examination

Method of measurement

Video records

5

Description

Degree of cry

Timepoint

30th and 60th second, 2nd minute for both eye examination, also 4th minute for right eye examination

Method of measurement

Video records

Intervention groups

1

Description

Neonates who were given distilled water 2 minutes before the procedure

Category

Placebo

2

Description

Neonates who were swaddled 15 minutes before the procedure

Category

Other

3

Description

Neonates who were given 0.6 ml 24% sucrose 2 minutes before the procedure.

Category

Other

4

Description

Neonates who were swaddled 15 minutes before the procedure and who were given 0.6 ml 24% sucrose 2 minutes before the procedure.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zeynep Kamil Maternity and Children's Education and Training Hospital

Full name of responsible person

Guner Karatekin

Street address

No:3-4, Dr. Burhanettin Üstünel Sokak., Zeynep Kamil Mah.

City

Istanbul

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Health Ministry Drug and Pharmacy General Management

Full name of responsible person

Saim Kerman

Street address

No:5, 2176. Sokak, Sögütözü Mahallesi

City

Ankara

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Health Ministry Drug and Pharmacy General Management

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