

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparison of the effect of oral sucrose application and kangaroo Mother care on some physiological variables and pain of venous blood sampling in premature Newborns admitted to Neonatal Intensive Care Units

Protocol summary

Study aim

Objective: Comparison of the effect of oral sucrose application and maternal kangaroo care on some physiological variables and pain score of venous blood sampling in premature newborns admitted to neonatal intensive care units

Design

A single blind randomized controlled clinical trial with two experimental groups and one control group was assigned to 22 newborns in each group.

Settings and conduct

Couples of the week will be referred to Hafez Hospital and individual days to Hazrat Zeinab Hospital for sampling. Newborns in the kangaroo care group receive kangaroo care by their mothers 30 minutes before blood sampling. In the oral sucrose group, 2 minutes before venous blood sampling 0.5ml the 24% oral sucrose solution is poured onto the anterior part of the newborns tongue using a syringe. Physiological variables and pain scores were measured in all three groups five minutes before, during and 5 minutes after venous blood sampling. The pain assessment is done by a nurse colleague who is not aware of the assignment of samples to the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Premature infants with gestational age of 28-28 (infant age not exceeding 37 weeks after birth) with stable clinical status. 2. No use of pain medication or non-medication for pain control during the past 24 hours 3. Age after birth 48 hours or more, so that the corrected age is not more than 37 weeks. Exclusion criteria: 1- Blood sampling from more than one place.

Intervention groups

The newborns in the experimental group consist of two groups. 22 newborns receiving maternal kangaroo care and 22 newborns receiving oral sucrose. newborns in the control group receive routine care and will receive no

intervention.

Main outcome variables

Heart rate, respiratory rate, arterial blood oxygen level, pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191215045749N1**

Registration date: **2020-03-29, 1399/01/10**

Registration timing: **prospective**

Last update: **2020-03-29, 1399/01/10**

Update count: **0**

Registration date

2020-03-29, 1399/01/10

Registrant information

Name

Narjes Nasri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-08, 1399/01/20

Expected recruitment end date

2020-07-10, 1399/04/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of oral sucrose application and kangaroo Mother care on some physiological variables and pain of venous blood sampling in premature Newborns admitted to Neonatal Intensive Care Units

Public title
The effect of oral sucrose on Premature Newborns pain
"; The effect of kangaroo Mother care on Premature Newborns pain; "

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Premature Infants with Gestational Age of 28-37(Infant Age not exceeding 37 weeks after Birth) with stable clinical status. Birth weight 1500 grams or more Absence of cardiac, respiratory, infectious, neurological and metabolic defects Apgar score of 7-10 at the first and fifth minutes Feeding the baby from the mouth. Failure to take painful measures one hour before starting study No intrauterine growth retardation Having a sucking reflex and response to painful stimulation. No infant with diabetes No necrotizing enterocolitis No use of pharmacological and non-pharmacological measures of pain control during the past 24 hours Age after birth 48 hours or more, so that the corrected age should not exceed 37 weeks. Maternal non-addiction to cigarettes, alcohol, and drugs during pregnancy. Moms with a good general outlook and a willingness to cooperate and not have a specific underlying illness in the mother
Exclusion criteria:
Blood sampling from more than one place.

Age
From **7 months** old to **8 months** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
The neonatal randomization was based on 3-digit permutation block method. ABC ACB BCA BAC CBA CAB
C: infants in control group A: infants in kangaroo care group B: Infants in oral sucrose group

Blinding (investigator's opinion)
Single blinded

Blinding description
In the two experimental groups, the pain score was

assessed by a nurse colleague with experience of working in the neonatal ward and not knowing the allocation of samples to the relevant groups by using the Neonatal Infant Pain Scale (NIPS). He is well trained. The nurse will assess the pain score by examining the recorded videos.

Placebo

Not used

Assignment

Parallel

Other design features

In this study, intravenous blood sampling is performed between 8 am and 9 am by a skilled and experienced neonatal staff in each hospital who is considered as a research assistant and will be stable during the study. Couples of the week will be referred to Hafez Hospital and individual days to Hazrat Zeinab Hospital for sampling.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran

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71348-14336

Approval date

2020-01-15, 1398/10/25

Ethics committee reference number

IR.SUMS.REC.1398.1197

Health conditions studied

1

Description of health condition studied

Pain from intravenous blood sampling in premature newborns

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain Score

Timepoint

5 minutes before, during and 5 minutes after venous blood sampling

Method of measurement

Neonatal Infant Pain Scale

2

Description

Respiration Rate

Timepoint

5 minutes before, during and 5 minutes after venous blood sampling

Method of measurement

Oximeter Pulse

3

Description

Heart Rate

Timepoint

5 minutes before, during and 5 minutes after venous blood sampling

Method of measurement

Oximeter Pulse

4

Description

Percentage of Arterial Blood Oxygen

Timepoint

5 minutes before, during and 5 minutes after venous blood sampling

Method of measurement

Oximeter Pulse

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Newborns in kangaroo care group receive kangaroo Mother Care 30 minutes before intravenous blood sampling

Category

Other

2

Description

Intervention group: In neonates of oral sucrose group, 2 min before intravenous blood sampling 0.5 ml of 24% oral sucrose solution is poured onto the anterior part of the tongue using a syringe.

Category

Other

3

Description

Control group: In the control group, routine care will be taken and will not receive any intervention before venous blood sampling

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Zeinab Hospital

Full name of responsible person

Zahra Nazari

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

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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, Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Email

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences - Fatemeh Nursing and Midwifery School

Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for general inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available