

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effect of neonatal massage on increasing the salivary secretory IgA level in premature infants with RDS diagnosis

Protocol summary

Study aim

The effect of neonatal massage on increasing the salivary secretory IgA level in premature infants with RDS diagnosis

Design

All preterm infants weighing between 1,500 and 2,000 grams who are suffering from RDS problems in Asalian, Shahid Madani and Shahid Rahimi hospitals in 1396 and are deprived of breast milk for any reason and use dry milk. Sampling: The infants were available and assigned to the study groups using stratified random blocks method (in order to identify gender probability). 75 neonates in each intervention and control group received 2-4 days after birth after acute RDS symptoms were resolved and when sIgA was prepared from saliva when used for milk preparation. The next sample will be received on the 14th birthday and will be recorded. During this period, the infants of the intervention group will be treated thoroughly 3 times a day, each time for 15 minutes by the trained expert.

Settings and conduct

This study is done in hospitals in Khorramabad, when have section has infants. Sampling: The infants were available and assigned to the study groups using stratified random blocks method (in order to identify gender probability). Blinding is not done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Preterm infants weighing between 1,500 and 2,000 grams admitted to the NICU of Asalian, Shahid Madani and Shahid Rahimi hospitals with RDS problems who are deprived of breast milk for any reason. Exit criteria: These infants are in need of treatment in case of sepsis (positive blood culture or other blood-positive parameters), need for IPPV, seizure, symptomatic PDA, history of weakened immune system in the family, infants with any malformations, minor or major, and babies with jaundice requiring blood replacement. Abnormalities are minor and major, and babies with jaundice requiring blood replacement

Intervention groups

Massage by child care clinicians

Main outcome variables

Increased secretion IgA level (SIGA) in preterm infants with RDS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171225038056N1**

Registration date: **2018-01-22, 1396/11/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-22, 1396/11/02**

Update count: **0**

Registration date

2018-01-22, 1396/11/02

Registrant information

Name

Majid Firouzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3322 3004

Email address

firouzi.m@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-17, 1395/01/29

Expected recruitment end date

2017-12-20, 1396/09/29

Actual recruitment start date

2017-12-20, 1396/09/29

Actual recruitment end date
2018-03-11, 1396/12/20

Trial completion date
empty

Scientific title
The effect of neonatal massage on increasing the salivary secretory IgA level in premature infants with RDS diagnosis

Public title
"The effect of neonatal massage on increasing the salivary secretory IgA level"

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Preterm infants weighing between 1,500 and 2,000 grams admitted to NICU at Asalian, ShahidMadani and ShahidRahimi Hospitals with RDS problems Babies who are deprived of milk for any reason and use dry milk
Exclusion criteria:
 Sepsis (positive blood culture or other positive blood parameters) Requires IPPV Seizure PDAs Symptoms require treatment A history of weakened immune systems in the family infants who have any malformations, both minor and major and babies with jaundice requiring blood replacement

Age
From **2 days** old to **14 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
 Target sample size: **150**
 Actual sample size reached: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
 accident cases were classified as simple random blocks due to elimination of the probability of sex in two groups of control and intervention

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Lorestan University of Medical Sciences
Street address
 Research and Technology Dept,Campus University Complex,Lorestan University of Medical Sciences,Koolimeter 5 Khorramabad Road, Tehran
City
 khorramabad
Province
 Lorestan
Postal code
 858575
Approval date
 2017-04-24, 1396/02/04
Ethics committee reference number
 IR LUMS.REC.1396.232

Health conditions studied

1

Description of health condition studied
 Infants with Respiratory distress syndrom

ICD-10 code
 P22.0

ICD-10 code description
 Respiratory distress syndrome of newborn

Primary outcomes

1

Description
 Saliva level of secretion IgA

Timepoint
 3 times a day every 15 minutes to 14 days

Method of measurement
 Saliva sampling (slgA)

Secondary outcomes

1

Description
 Normal breathing

Timepoint
 14 days

Method of measurement
 Ventilator

2

Description
 Added weight in newborns

Timepoint
 14 days

Method of measurement
 Scales

Intervention groups

1

Description

Intervention group: Babies massage therapy 2-4 days with respiratory distress daily 3 times

Category

Treatment - Other

2

Description

Control group: Infants with respiratory distress 2-4 days after birth

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Asli Charity Hospital

Full name of responsible person

Dr.masoumeh ghafarzadeh

Street address

Asli Charity Hospital, Corner of the street, Twelfth Street, Cui Palestine

City

Khorramabad

Province

Lorestan

Postal code

68559878

Phone

+98 66 3322 3030

Email

asali.hospital@lums.ac.ir

2

Recruitment center

Name of recruitment center

Shahid Rahimi Hospital

Full name of responsible person

Dr majidabdollahian

Street address

Shahid Rahimi Hospital, Azadi Avenue, Khorramabad, Iran

City

Khorramabad

Province

Lorestan

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858570

Phone

+98 66 3333 6138

Email

pr@lums.ac.ir

3

Recruitment center

Name of recruitment center

Shahid Madani Hospital

Full name of responsible person

Dr.majid firouzi

Street address

Shaheed Madani Hospital, Kheyraabad Ave., Khorramabad, Iran

City

khorrarnabad

Province

Lorestan

Postal code

858795

Phone

+98 66 3343 7164

Email

dr.firouzai@lums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

dr.morovat taheri kalani

Street address

Deputy of research and technology, Campus complex, Lorestan University of Medical Sciences, 5 km Khorram Abad-Boroujerd

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khorrarnabad

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Lorestan

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381251698

Phone

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Email

research@lums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khoram-Abad 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

Person responsible for general inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr.majid firouzi

Position

Infants Specialty

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Neonatal group, Shaheed Madani Hospital, Kheirabad

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Lorestan

Postal code

858795

Phone

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Email

firouzi.m@lums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr.majid firouzi

Position

Infants Specialty

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Neonatal group, Shaheed Madani Hospital, Kheirabad

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858795

Phone

+98 66 3343 7164

Email

firouzi.m@lums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Elham Shikhey

Position

Research expert

Latest degree

Bachelor

Other areas of specialty/work

Library and Medical Information

Street address

Clinical Research Unit, Department of Clinical,
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khorrarnabad

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Email

nedaesh1@yahooo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data after Unidentifiable Can be Publication

When the data will become available and for how long

Start the access period 12 months after printing the results

To whom data/document is available

Data will only be available for doctors, nurses and midwives

Under which criteria data/document could be used

The analyzes concerning the outcomes of the plan are for the benefit of doctors, nurses and midwives of their positive outcomes

From where data/document is obtainable

00989163979788-email: nedaesh1@yahoo.com Elham Shikhey

What processes are involved for a request to access data/document

Send email To responsive person

Comments