Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 1,500and2,000 grams who are suffering from RDS problems in Asalian, ShahidMadani and ShahidRahimi 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 (sIgA)

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
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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 majidabdolahian
Street address
Shahid Rahimi Hospital, Azadi Avenue, Khorramabad, Iran
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Khorramabad
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858570
Phone
+98 66 3333 6138
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3

Recruitment center
Name of recruitment center
Shahid Madani Hospital
Full name of responsible person
Dr.majid firouzi
Street address
Shaheed Madani Hospital, Kheyrabad Ave., Khorramabad, Iran
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khorramabad
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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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khorramabad
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381251698
Phone
+98 66 3312 0172
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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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

Street address
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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, Shohada Hospital

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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