

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

A Clinical trial to compare the effects of topical sunflower oil and massage in preventing nosocomial infections in preterm infants

Protocol summary

Study aim

This study aimed to study effect of sunflower oil for prevention of nosocomial infection among preterm neonates.

Design

This randomized clinical trial was performed on 60 premature infants (<34 week gestation) hospitalized in the NICU, Ghaem hospital. The patients were randomly assigned to two sunflower oil massage (n=27) and control group (n = 33) based on random numbers. The body surface of infants was massaged by sunflower oil, 3 times a day up to 2 weeks and then twice a day until 28 days.

Settings and conduct

In this questionnaire, confounding factors such as underlying illness, drug intake, etc. were considered and the neonates with these factors were excluded from the study. Initial blood cultures were done for all newborn infants and secondary blood cultures were performed for infants with suspected systemic infection. The status of the skin was assessed on days 1, 3, 7, 14, 21 and 28.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Premature infants (<34 week or <1800 gr). Exclusion Criteria: Neonates requiring mechanical ventilation; Major anomalia in neonates; Extensive surgery; Known immunodeficiency defects; death within 48 hours of entering research.

Intervention groups

Sunflower oil massage for intervention group and massage without oil for control group were used.

Main outcome variables

Nosocomial infections

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130120012197N3**

Registration date: **2017-12-03, 1396/09/12**

Registration timing: **retrospective**

Last update: **2017-12-03, 1396/09/12**

Update count: **0**

Registration date

2017-12-03, 1396/09/12

Registrant information

Name

Maryam Zakerihamidi

Name of organization / entity

Tonekabon Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 19 1224 5014

Email address

maryamzakerihamidi@yahoo.co.nz

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2010-03-21, 1389/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical trial to compare the effects of topical sunflower oil and massage in preventing nosocomial infections in preterm infants

Public title

Effect of topical sunflower oil in preventing nosocomial infections

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Premature infants (<34 week or <1800 gr)

Exclusion criteria:

Neonates requiring mechanical ventilation Major anomaly in neonates Extensive surgery Known immunodeficiency defects death within 48 hours of entering research

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done using random numbers.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization is done using random numbers.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences, Mashhad, Iran

Street address

Mashhad University of Medical Sciences, Daneshgah Ave., Mashhad, Iran

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Province

Razavi Khorasan

Postal code

4661734666

Approval date

2006-08-29, 1385/06/07

Ethics committee reference number

IR.MUMS.REC.1385.152

Health conditions studied**1****Description of health condition studied**

Status of cutaneous

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Nosocomial Infections

Timepoint

1, 3, 7, 14, 21 and 28 days after birth

Method of measurement

Blood Culture

Secondary outcomes**1****Description**

Duration Hospitalization

Timepoint

1, 3, 7, 14, 21 and 28 days after birth

Method of measurement

Days of hospitalization

2**Description**

Duration of hospitalization

Timepoint

Up to discharge time

Method of measurement

Number

Intervention groups**1****Description**

Use of Golshad sunflower seed oil of Kashmar. in the NICU hospital Ghaem two oil massage sunflower oil (n=27) and controls (n = 33) were performed. The body surface of infants up to 2 weeks and then twice to three times daily for 28 days with sunflower oil

Category

Prevention

2**Description**

Control group: Lack of massage with sunseed oil

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Ghaem Hospital

Full name of responsible person

Mostafa Dastani

Street address

Ghaem Hospital and Research Center, Ahmad Abad Ave, Dr Shariati Square (Taghi Abad), Mashhad, Khorasan Razavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Ghoreishi Building, Daneshgah Av., Mashhad

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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

The Mashhad 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

Islamic Azad University

Full name of responsible person

Maryam Zakerihamidi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Pediatrics

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available