

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of two and twenty four hour treatment with salt in infant's Umbilical Granuloma

Protocol summary

Summary

One of the most common umbilical problems in neonates is umbilical granuloma, causing inflammation and drainage. This study was carried out to compare the effect of 2 and 24 hours salt (NaCl) in the treatment of neonatal umbilical granuloma. This is a controlled clinical trial study, done at neonatal NICU and infant Follow-up clinic of Emamreza hospital, Mashhad university of Medical sciences. 40 Neonates were randomly assigned to one of two groups. Group 1, including 20 infants with umbilical granuloma was undergone 24 hours treatment with salt group 2, including 20 infants was undergone 2 hours treatment with salt. In the first the salt was not washed out and or cleaned during this period. In the second group, the salt was washed by boiled water every 2 hours. The neonates were visited every day and healing process will be recorded. If there was no sign of healing, treatment with salt was continued until full recovery. Separation of umbilical cord and side effects was compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138710021378N2**

Registration date: **2009-12-05, 1388/09/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-12-05, 1388/09/14

Registrant information

Name

Ahmadshah Farhat

Name of organization / entity

Neonatal Research Center of Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 1121

Email address

farhata@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2005-12-31, 1384/10/10

Expected recruitment end date

2006-12-31, 1385/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two and twenty four hour treatment with salt in infant's Umbilical Granuloma

Public title

Comparison of two and twenty four hour treatment with salt in infant's Umbilical Granuloma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All neonates less than 1 month that were admitted in NICU or referred to clinic of Emamreza hospital. Exclusion criteria: Presence of respiratory disorder, skin disorder, or infection diseases, very low birth weight neonates (birth weight less than 1500 grams)

Age

No age limit
Gender
Both
Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
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

Vice-chancellor for Research, Mashhad University of
Medical Sciences

Street address

Ghoreishi building, Daneshgah street

City

Mashhad

Postal code

91379-13131

Approval date

2008-12-14, 1387/09/24

Ethics committee reference number

5/9404

Health conditions studied

1

Description of health condition studied

umbilical granuloma

ICD-10 code

P38

ICD-10 code description

Omphalitis of newborn with or without mild haemorrhage

Primary outcomes

1

Description

healing time of granuloma

Timepoint

Baseline and everyday till improvement of granuloma

Method of measurement

Observation of healing time by researcher

2

Description

Separation of umbilical cord

Timepoint

daily

Method of measurement

by observation

3

Description

side effects

Timepoint

daily

Method of measurement

Observation of redness, irritation, or inflammation

Secondary outcomes

empty

Intervention groups

1

Description

Granuloma was irrigated with boiled water and then was
covered with powder of salt every 24 hours

Category

Treatment - Other

2

Description

Granuloma was irrigated with boiled water and then was
covered with powder of salt every 2 hours

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Neonatal Research Center

Full name of responsible person

Ahmad shah Farhat

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Tavakol Afshari

Street address

Ghorashi building, Daneshjoo street

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

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

Neonatal Research Center

Full name of responsible person

Dr. Ahmadshah Farhat

Position

Neonatologist, assistant professor

Other areas of specialty/work

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Person responsible for updating data

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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