

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Effectiveness of Baby's Washing and Massage in Physiological Jaundice in Infants

Protocol summary

Study aim

Determination of the effect of washing the baby and massage on the physiological jaundice in newborns

Design

In this research 90 newborns are born Association were chosen purposefully Then, newborns , were randomly divided into three control and intervention groups.

Settings and conduct

A study was conducted on the effect of infant washing and massage on physiological jaundice in Ardakan Ziaee Hospital. Birth children were randomly divided into three groups. The study was a blind clinical trial and the assistant was blind to the data.

Participants/Inclusion and exclusion criteria

Admission criteria: Apgar score greater than 7 and gestational age 38 to 42 weeks, weight greater than 2500 g, Clear anomalies Exit criteria: Apgar 7 and under 7, admission to the newborn

Intervention groups

Massage group: Massage was performed twice a day for 5 days Washing group :Babies were washed immediately after birth Control group: Infants received routine care

Main outcome variables

Both massage and washing stimulate the secretion of gastrin, prevent breast feeding and reduce the physiologic jaundice.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170911036118N1**

Registration date: **2018-01-17, 1396/10/27**

Registration timing: **retrospective**

Last update: **2018-01-17, 1396/10/27**

Update count: **0**

Registration date

2018-01-17, 1396/10/27

Registrant information

Name

Effat Noroozi

Name of organization / entity

Shahid Sadoughi University of Yazd

Country

Iran (Islamic Republic of)

Phone

+98 35322246041

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Recruitment status

Recruitment complete

Funding source

Yazd University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

2017-02-19, 1395/12/01

Actual recruitment end date

2017-05-20, 1396/02/30

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Baby's Washing and Massage in Physiological Jaundice in Infants

Public title

' Effect of Massage and Washing in Physiological Jaundice"

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All babies born with fetal age range 37 to 42 weeks weight more than 2500 grams Apgar above 7 after birth lack of obvious congenital anomaly

Exclusion criteria:

Pathological jaundice, Baby hospitalization, Canceling the plan

Age

From **1 day** old to **7 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **90**

Actual sample size reached: **71**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization
Randomization tool: Wax sealed. Three envelopes were placed inside the envelopes 1, 2 and 3. The investigator randomly selected one of the envelopes and determined by the number inside the group in which the baby was placed.

Blinding (investigator's opinion)

Not blinded

Blinding description

It was a blind one study. The investigator's assistant checked the bilirubin on the prescribed days, and was unaware of the groups.

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd University of Medical Sciences

Street address

Yazd University of Medical Science; Alam Square, Safayeh, sYazd

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2016-12-25, 1395/10/05

Ethics committee reference number

1395.224IR.SSU.REC

Health conditions studied

1

Description of health condition studied

Physiological jaundice

ICD-10 code

P70-P74

ICD-10 code description

XVI Certain conditions originating in the perinatal period

Primary outcomes

1

Description

Neonatal jaundice

Timepoint

Day 1, 3, 5 and 7

Method of measurement

Check out the Billy checker

Secondary outcomes

1

Description

Baby washing

Timepoint

Day 1, 3, 5 and 7

Method of measurement

Biliometer

2

Description

Baby massage

Timepoint

Day 1, 3, 5 and 7

Method of measurement

Biliometer

Intervention groups

1

Description

Bath group were bathed immediately after birth

Category

Prevention

2

Description

massage group for five days, tow times each day , every

time for 15 minutes

Category

Prevention

3

Description

the control group received routine care

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ziaie Hospital

Full name of responsible person

Effat Noroozi

Street address

Ziaie Hospital, Teachers' Square, Azadi Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mehrdad Mansoori

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Effat Noroozi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Data will be available to researchers working in academic and academic institutions and students

Under which criteria data/document could be used

Data is available for students to help investigate similar projects while retaining the contents

From where data/document is obtainable

To receive data at e.noroozi@yahoo.com And call the phone 09132517951

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

After receiving the application for data, the applicant will be provided with the documentation within two days

Comments