

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Evaluation of the effect of baby massage on reducing neonatal jaundice in healthy neonates born in delivery ward of Vali-asr hospital in 1392-1393

Protocol summary

Summary

This Interventional study aims to evaluate the effect of baby massage on reducing Neonatal jaundice , in 50 neonates. Firstly general information including gestational age, APGAR score, birth weight, sex, number of previous deliveries, and type of delivery is recorded in neonates who meet the inclusion criteria. Then massage is taught to the mothers by educated personnel. Massage is started at day one and continued until day 5. Neonates in the therapy group are massaged twice a day by their mothers(each time 15 minutes). Massage is performed with bare, clean, washed hands,starting with two fingers on the cheeks and around the eyes then moving to the chest and the abdomen with semicircular moves, after that is the extremities and at last the back on both sides of the vertebral column. The massage method is taught to the mothers after the labor and a notebook is given to them in order to record times of massage, times of defecation, and it is advised to both groups to refer to the hospital on 4th day postpartum to check a transcutaneous bilirubin(by the Bilitest) on day 4. Times of defecation is also recorded on day 1-4. In case of admission or the need for phototherapy during the trial , that neonate will be excluded from the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201401089568N6**
Registration date: **2014-02-16, 1392/11/27**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-02-16, 1392/11/27

Registrant information

Name

Golnaz Rezaeizadeh

Name of organization / entity

Maternal Fetal Neonatal Research Center,Tehran
University of Medical Sciences, Tehran, Iran

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2357

Email address

mfnhrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University Of Medical Sciences-Research Project

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of baby massage on reducing neonatal jaundice in healthy neonates born in delivery ward of Vali-asr hospital in 1392-1393

Public title

Effect of baby massage on reducing neonatal jaundice

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: gestational age of 37-41 weeks, birth

weight of more than 2500 grams, APGAR score of 8-10(1st and 5th minute), being healthy on all other aspects
Exclusion criteria: neonatal jaundice at a level that requires admission and therapy(including phototherapy), presence of asphyxia in neonate(characterized by a umbilical artery Ph of below 7), ABO/Rh incompatibility, G6PD deficiency, induction of labor , suffering from uterine atony after delivery, caesarian section performed because of absence of labor progression, history of blood exchange due to jaundice in a previous child.

Age

From **1 year** old to **2 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

TUMS-Research Deputy

Street address

TUMS-Ghods st., Keshavarz blvd

City

Tehran

Postal code

14197

Approval date

2014-01-07, 1392/10/17

Ethics committee reference number

24489

Health conditions studied

1

Description of health condition studied

Neonatal jaundice

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

Serum bilirubin level

Timepoint

Day 4

Method of measurement

Miligram per desilitre in blood test

Secondary outcomes

1

Description

Defecation time

Timepoint

After intervention

Method of measurement

Asking mother

Intervention groups

1

Description

Therapy(Intervention) group: Baby massage is taught to the mothers by a professional personal. it is emphasized that mothers should wash their hands thoroughly up to the elbows before starting the massage. Massage is started on the first day of birth and is continued until the 5th day. Neonates in the therapy group are massaged twice every day for a period of 15 minutes each time, massage is performed using baby oil and bare clean washed hands.Starting with 2 fingers from the face and around the eyes and cheeks then the chest , then the abdomen with semicircular moves and finally the extremities and the back(both sides of the vertebrae).

Category

Prevention

2

Description

control group: standard methods, massage is not performed and routine care is given.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

vali-asr hospital

Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Maternal,Fetal & Neonatal Research Center
Full name of responsible person
Dr. mamak shariat
Street address
Imama Khomeini hospitals complex,Tehran
City
Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Maternal,Fetal & Neonatal Research Center

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
Maternal,Fetal & Neonatal Research Center
Full name of responsible person
Edit Haghazarian
Position
Medical student
Other areas of specialty/work
Street address
No.29, 2nd St., Homaei ave., Resalat Blvd.
City
Tehran
Postal code
1633835461
Phone
+98 21 8841 6249
Fax
Email
edith.hagh@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Breastfeeding Research Center
Full name of responsible person
Hosein Dalili
Position
Assistant Professor
Other areas of specialty/work
Street address
Vali-Asr Hospital
City
Tehran
Postal code
14197
Phone
+98 21 6659 1316
Fax
Email
hoseindalili@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Maternal,Fetal and Neonatal Research Center
Full name of responsible person
Edith Haghazarian
Position
Medical Student
Other areas of specialty/work
Street address
No.29, 2nd St. Homaii Ave. Resalat Blvd.
City
Tehran
Postal code
1633835461
Phone
+98 21 8841 6249
Fax
Email
edith.hagh@gmail.com
Web page address

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