

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison the effect of Gentle Human Touch and Massage Techniques, Field, on urine cortisol hormon in preterm infants: Randomized Control Clinical Trial

Protocol summary

Summary

The aim of this study is to compare the effect Gentle Human Touch and Massage Techniques, Field, on urine cortisol hormon in preterm infants.this study is a Randomized Control Clinical Trial.in this study will be using check list for the record demographic information and results laboratory(measurement cortisol in Twenty-four-hour urine)for determine level stress. . About 84eligible infants (30-36 weeks gestational age) will be randomly divided into three groups.The subjects in first group will be thouched 3 times a day for 15 minutes for5 days by mothers. In the second group, the subjects will be messaged in accordance with field message technique, 3 times a day for 15 minutes with use of sunflower oil for5 days by mothers. The subjects in third group will receive routine massage in word.in three group Twenty-four-hour urine cortisol samples were collected both before and after the 5-day intervention period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407275168N5**

Registration date: **2014-08-19, 1393/05/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-19, 1393/05/28

Registrant information

Name

Maliheh Assadollahi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Gentle Human Touch and Massage Techniques, Field, on urine cortisol hormon in preterm infants: Randomized Control Clinical Trial

Public title

Effect of Touch and Massage on urine cortisol hormon in preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:30-36 gestational ages, 7-10 day passed from Date of Birth,Infants cared in cut or incubator that under any means for respiratory ventilation such as nasal cannula, positive pressure applied through the nose, mask, and not

ventilator. Infants cared in cut or incubator that not intravenous or intramuscular medication instructions or blood sampling, and only remained in word due to access weight. Exclusion criteria: If have symptoms like (fever, respiratory distress, muscle stiffness, vomiting) infant massage will stop. If infant was allergy to sunflower oil. If cases such as intraventricular hemorrhage, necrotizing enterocolitis, patent ducts arteriosus, sepsis, acute lung disease or anemia (Hb < 10 gm/dl) found during the study. Infants that their mothers not regular perform massage or therapeutic touch program on schedule (at least once a day for 5 day), be excluded of study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 84

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

Tabriz University of Medical Sciences

Street address

Central Building of Tabriz University of Medical Sciences, Golgasht Avenue, azadi street, Tabriz

City

Tabriz

Postal code

Approval date

2014-07-14, 1393/04/23

Ethics committee reference number

9364

Health conditions studied

1

Description of health condition studied

stress in premature infants

ICD-10 code

F43.9

ICD-10 code description

Reaction to severe stress, unspecified

Primary outcomes

1

Description

decrease cortisol in Massage by Techniques, Field

Timepoint

before and after the 5-day intervention period

Method of measurement

The concentration of cortisol was measured by Radio Immuno Assay (cemilominesanse) by liasow device

Secondary outcomes

1

Description

decrease cortisol in gentle touch

Timepoint

before and after the 5-day intervention period

Method of measurement

The concentration of cortisol was measured by Radio Immuno Assay (CEMILOMINOSANS) by LIASOW device

Intervention groups

1

Description

The newborns in control group will receive routine massage and no intervention will be performed on them.

Category

N/A

2

Description

Gentle Touch group: For 15 min, the mother placed the fingertips of one hand above the eyebrow line with the palm touching the preterm infant's crown while the other hand was rested on the lower abdomen of the infant encompassing the waist and the hip.

Category

Prevention

3

Description

Massage Techniques, Field group: tactile and kinesthetic stimulation will carry out in 15-minute sessions. Each session consisted of 3 standardized phases of 5 minutes each, in which the infants were keep in a prone position in the 1st and 3rd phase. The neonates will gently stroke with the soft, smooth surfaces of all the fingers of both hands. The tactile stimulation procedure included 12 strokes at a rate of approximately 5 seconds per stroking

motion over each region of the neonate in the following sequence: From the top of the head down the sides of the face to the neck, and vice versa; From the back of the neck to both ends of the shoulders, and vice versa; From the thighs down to the ankles, and vice versa; From the shoulders down the arms to the wrist, and vice versa. In the middle phase, the neonate will make to lie in a supine position for kinesthetic stimulation that included 5 segments of 1 minute each which consist of 6 passive flexion/extension movements, each lasting 10sec. The stimulation will do on each arm, then each leg and lastly both legs together.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Educational Center Affiliated Tabriz university of Medical Sciences ;Iran

Full name of responsible person

sakine ibrahimi

Street address

Bagshomal Square

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Science

Full name of responsible person

Malihe Assadollahi

Street address

Department of Pediatrics, School of nursing and Midwifery, Tabriz

City

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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

Tabriz University of Medical Science

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

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Full name of responsible person

Malihe Assadollahi

Position

MSc in pediatric Nursing

Other areas of specialty/work

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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*