

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### **A comparative study of abdominal and field massage on physiological indicators, weight gain, and digestive function of preterm infants admitted to neonatal intensive care units: A randomized controlled clinical trial**

#### **Protocol summary**

##### **Study aim**

Comparison of the effects of abdominal and field massage on physiological indicators, weight gain, the digestive function of premature newborns admitted to neonatal intensive care units

##### **Design**

A randomized clinical trial with a control group with three parallel arms will be conducted with 90 participants. The allocation sequence will be determined by a computer program with block sizes of 3 to 9 with an allocation ratio of 1:1:1. Allocation concealment will be centralized.

##### **Settings and conduct**

This clinical trial will be conducted on 90 premature neonates from the NICU of Shiraz University of Medical Sciences. The massage group will receive abdominal and field massage before feeding, twice a day, for 15 minutes, over 5 days, by the researcher. The control group will receive only routine care. In both abdominal and field massage groups, olive oil will be used for massage. In the I Love You massage group, the baby lies on his/her back with a head angle of 30 to 45 degrees. Abdominal massage will be applied in a clockwise direction above the intestinal area. In the field massage group, each massage will consist of 3 phases of 5 minutes and will be 15 minutes in total. All preterm neonates are fed with a nasogastric tube - French 6 or 8. The feeding protocol will be the same for all neonates.

##### **Participants/Inclusion and exclusion criteria**

Primary inclusion criteria: The neonate should be in the first 48 hours after birth; a 5th-minute Apgar score of 7 or higher; gestational age between 30 to 34 weeks; and weight between 1000 and 1750 grams. Primary exclusion criteria: cleft palate and lip, contraindication for massage, premature newborns with congenital anomalies, recent abdominal surgery.

##### **Intervention groups**

Field massage group; abdominal massage group; control group

##### **Main outcome variables**

Physiological indicators, weight gain, and digestive function

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20221220056884N1**

Registration date: **2023-04-28, 1402/02/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-04-28, 1402/02/08**

Update count: **0**

##### **Registration date**

2023-04-28, 1402/02/08

##### **Registrant information**

##### **Name**

Sedigheh Khodabandeh Shahraki

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 34 3132 5220

##### **Email address**

mitra.khodabandeh@yahoo.com

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2023-02-20, 1401/12/01

**Expected recruitment end date**

2023-09-21, 1402/06/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A comparative study of abdominal and field massage on physiological indicators, weight gain, and digestive function of preterm infants admitted to neonatal intensive care units: A randomized controlled clinical trial

**Public title**

A comparative study of abdominal and field massage on physiological indicators, weight gain, and digestive function of preterm infants

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

The baby being in their first 48 hours after birth Feeding through a nasogastric tube - French 6 or 8 5th-minute Apgar being 7 or higher Gestational age between 30 to 34 weeks Absence of severe respiratory distress Weight between 1000 and 1750 grams No need for ventilation Absence of mother's addiction

**Exclusion criteria:**

Cleft palate and lip Any prohibition for massage All preterm infants with congenital abnormalities such as congenital heart disease, gastrointestinal tract abnormalities, hypoxic injury, respiratory failure, current or past history of necrotizing enterocolitis, suspected or confirmed sepsis Recent abdominal surgery

**Age**

From **2 days** old to **28 days** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Premature babies in the NICU department who have the conditions to enter the study, using the random block method with the size of blocks of 3 and 9, including (abdominal massage group, field massage and control group) with a 1:1:1 allocation ratio in one of the groups Intervention and control will be placed. Allocation sequence will be determined using the computer program www.Random.org by a person not involved in the selection of the samples.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The evaluation of the outcome will be made by someone who is blinded to 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 Kerman University of Medical Sciences

**Street address**

Haft Bagh Alavi, Pardizeh, Kerman University of Medical Sciences

**City**

Kerman

**Province**

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**Postal code**

7616913555

**Approval date**

2023-02-27, 1401/12/08

**Ethics committee reference number**

IR.KMU.REC.1401.540

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

Preterm newborn

**ICD-10 code**

P07.3

**ICD-10 code description**

Preterm [premature] newborn [other]

**Primary outcomes****1****Description**

Physiological indicators

**Timepoint**

Before the intervention, after the intervention

**Method of measurement**

Saadat Monitoring Machine

**2****Description**

weight gain

**Timepoint**

Before the intervention, after the intervention

**Method of measurement**

Seca scale made by Persia factory

**3****Description**

Digestive function

**Timepoint**

Before the intervention, after the intervention

**Method of measurement**

Syringe

**Secondary outcomes**

empty

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

Intervention group 1: The masseur in the intervention group gives her baby abdominal massage for 15 minutes at a certain time (9:00 a.m. and 9:00 p.m.) on five consecutive days (as trained).

**Category**

Treatment - Other

**2****Description**

Intervention group 2: The masseur gives her neonetals a field massage for 15 minutes at a certain time (9:00 am and 9:00 pm) on five consecutive days (as trained).Field massage is such that each massage will consist of 3 phases of 5 minutes and a total of 15 minutes, in the first and third phase, the baby will be placed on the stomach and the massage will be performed as follows: 1) from the top of the head to the neck and vice versa, 2) from the neck to the shoulders and vice versa, 3) from the upper back to the waist and vice versa, 4) from the shoulder to the hand and then in the reverse direction in both hands, 5) from the thigh to the ankle leg and then in the reverse direction on both legs. In each of the mentioned areas, 12 movements of 5 seconds will be performed. In the second phase, the baby will be in the vault position and the passive movements of flexion and extension of the arms and legs separately and both legs together will be performed in 5 stages of one minute, each stage will include 6 movements of 10 seconds.

Takes

**Category**

Treatment - Other

**3****Description**

Control group: Newborns in the control group will receive the routine NICU care.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Afzalipur Hospital

**Full name of responsible person**

Golnoush Motamedi

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Afzalipur Hospital, Imam Khomeini Highway

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http://ah.kmu.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Davood Kalantar-Neyestanaki

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

personal

**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**

Kerman University of Medical Sciences

**Full name of responsible person**

Golnoush Motamedi

**Position**

Master's student in Neonatal Intensive Care Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Sedigheh Khodabande Shahraki

**Position**

Assistant Professor

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Ph.D.

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

golnoush motamedi

**Position**

Master's student in Neonatal Intensive Care Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is still no plan to develop a program for sharing the data. According to the above sampling data time, the study will be completed by that time.

**Study Protocol**

No - There is not 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