

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The effect of Kangaroo Mother Care on Primary outcome in Preterm Infants:A Controlled randomized clinical trial

Protocol summary

Summary

The purpose of this study was to evaluate The effect of Kangaroo Mother Care on Primary outcome in Preterm Infants. It is was a single blind study, so that the researchers were not blind but the executive nurse was blind. In this study, 140 infants aged 30-34 weeks with weight>1000g were randomly divided into two groups. The infant in intervention group at least 5 days a week and every half hour during the day and four times receive KMC. The infant in control group within the incubator and the incubator are not removed except for feeding. Finally, outcomes(Blood sugar, weight, height and head circumference) from baseline to discharge will be measured and compared in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201303134617N5**

Registration date: **2013-03-21, 1392/01/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-03-21, 1392/01/01

Registrant information

Name

Mahnaz Jabraeili

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Deputy of Research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Kangaroo Mother Care on Primary outcome in Preterm Infants:A Controlled randomized clinical trial

Public title

The effect of Kangaroo Mother Care on Primary outcome in Preterm Infants:A Controlled randomized clinical trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age infants 34 to 30 weeks of pregnancy; nutrition, exclusive breastfeeding through PO / NGT; no chromosomal abnormalities and congenital anomaly; 5-minute Apgar score of 7; stability physiological birth; weighing more than 1000 grams' mother's mental and physical fitness to participate in the study. Exclusion criteria: if symptoms such as bradycardia and loss of maternal care during KMC; intervention and were excluded from the study will be stopped; if mothers arms control tend to be taken care of samples will be removed.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **70****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 Ethics Committee

Street address

Deputy of Research, Tabriz University of Medical Sciences ,Golgasht street , Tabriz,East Azarbaijan

City

Tabriz

Postal code**Approval date**

2013-03-09, 1391/12/19

Ethics committee reference number

11453/4/5

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

Kangaroo Mother Care outcome

ICD-10 code

Z00-Z99

ICD-10 code description

Health supervision and care of other healthy infant and child

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

weight gain preterm infant

Timepoint

From baseline to discharge

Method of measurement

Using Seca scale with a precision of 10 g

Secondary outcomes**1****Description**

Blood Sugar

Timepoint

From baseline to discharge

Method of measurement

Glcometr ACCU_CHEK Model GC

2**Description**

height infant

Timepoint

From baseline to discharge

Method of measurement

centimeter

3**Description**

Head circumference infant

Timepoint

From baseline to discharge

Method of measurement

centimeters

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

The infant in intervention group at least 5 days a week and every half hour during the day and four times receive KMC

Category

Other

2**Description**

The infant in control group within the incubator and the incubator are not removed except for feeding

Category

Treatment - Drugs

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

29 bahman Hospital

Full name of responsible person**Street address**

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of research, Tabriz University of Medical Sciences

Full name of responsible person

Dr Ostad Rahimi

Street address

Research Department, Central Building , Golgasht ,
Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of research, Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Alehe Seyyedrasooly

Position

MSc , Faculty member

Other areas of specialty/work

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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