Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of Kangaroo mother care and conventional method in premature of less than 2000 grams birth weight in weight gaining, clinical cyanosis, mother confidence, hospitalization and nosocomial infections

Protocol summary

Summary
Objective: The aim of study was to compare the effect of Kangaroo mother care (KMC) and conventional methods of care (CMC) in premature low birth weight babies less than 2000 grams birth weight in weight gaining, clinical cyanosis, mother confidence, hospitalization and nosocomial infections. Method: One hundred babies with birth weight less than 2000 grams and without clinical problem will randomly divided in two groups, the intervention group (N=50) receive Kangaroo mother care and the control group (N=50) receive conventional care. Two groups will compare in daily weight gaining, self confidence of mother, duration of hospitalization, clinical cyanosis and nosocomial infections.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT201101091162N16**
Registration date: **2011-02-10, 1389/11/21**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2011-02-10, 1389/11/21

Registrant information
Name
Ashraf Mohammadzadeh
Name of organization / entity
Neonatal Research Center of Mashhad University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 51 1852 1121
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Recruitment status
Recruitment complete
Funding source
Mashhad university of medical sciences

Expected recruitment start date
2007-03-07, 1385/12/16
Expected recruitment end date
2009-01-31, 1387/11/12
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Kangaroo mother care and conventional method in premature of less than 2000 grams birth weight in weight gaining, clinical cyanosis, mother confidence, hospitalization and nosocomial infections

Public title
Comparison of Kangaroo mother care and conventional method in premature of less 2000 grams birth weight in weight gaining, clinical cyanosis, mother confidence, hospitalization and nosocomial infections
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Babies with birth weight less than 2000 gr which were stabilized in first 72 hr of age Exclusion criteria: babies with requiring ventilator support,

suffering from apnea, unstable temperature, and intravenous nutrient

Age
From **2 years** old to **28 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

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
Vice chancellor for research of Mashhad University of medical sciences

Street address
Ghoreshi building, Daneshgah street

City
Mashhad

Postal code
13131-91379

Approval date
2006-12-26, 1385/10/05

Ethics committee reference number
11471/51

Health conditions studied

1

Description of health condition studied
nosocomial infection

ICD-10 code
Y95

ICD-10 code description
Nosocomial condition

2

Description of health condition studied
duration of hospitalization

ICD-10 code
Z59.3

ICD-10 code description
Problems related to living in residential institution

3

Description of health condition studied
weight gaining

ICD-10 code
R62.8

ICD-10 code description
Other lack of expected normal physiological development

4

Description of health condition studied
self confidence of mother

ICD-10 code
F69

ICD-10 code description
Unspecified disorder of adult personality and behaviour

5

Description of health condition studied
cyanosis

ICD-10 code
R23.0

ICD-10 code description
Cyanosis

Primary outcomes

1

Description
weight gaining

Timepoint
daily

Method of measurement
with scale

2

Description
mother confidence

Timepoint
daily

Method of measurement
clinical

3

Description
hospitalization

Timepoint
daily

Method of measurement
at discharge

4

Description
cyanosis
Timepoint
daily
Method of measurement
clinical

5

Description
nosocomial infections
Timepoint
daily
Method of measurement
positive culture of blood, CSF, Urine

Secondary outcomes

1

Description
temperature instability
Timepoint
q 6 hours
Method of measurement
with termometer

Intervention groups

1

Description
kangaroo mother care
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
neonatal research center of Mashhad university of medical sciences
Full name of responsible person
Dr.Ashraf Mohammadzadeh
Street address
Neonatal research center- NICU- Emamreza hospital
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad university of medical sciences
Full name of responsible person
Dr Jalil Tavakol Afshari
Street address
Ghoreshi bulding, Daneshgah street
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Neonatal Research Center
Full name of responsible person
Dr. Ashraf Mohammadzadeh
Position
Neonatologist, professor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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