

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effects of kangaroo mother care on the level of bilirubin in the newborn after cesarean and maternal satisfaction from care after birth

Protocol summary

Summary

The purpose of this study was determine effects of kangaroo mother care on level of bilirubin newborns after cesarean and satisfaction mothers from care after birth. The study is single blind. The samples were placed randomly in two groups control and intervention. The study population included mothers and infants from cesarean delivery admitted in the women surgical ward of Fatima Hospital in the City Miyandoab. Inclusion criteria newborns were term, cesarean delivery, and mothers criteria receive spinal anesthesia. If during study the newborns have respiratory distress or pathological jaundice will be excluded. Mother use antidepressants or drug, have a history prior experience kangaroo mother care, diabetes and hypertension will be excluded. The number of samples is fifty eight for each group. The intervention group infants received kangaroo mother care immediately after birth, and this act repeated at hours 7, 13 and 19 later days, and control group infants receive routine care. Bilirubin both groups of babies at birth, 24 hours, 36 hours and the fifth day after birth from the forehead with Billy Check control and will compared. Mother's both groups receive satisfaction questionnaire from care after birth on the discharge day from hospital (third day), and will compare. The intervention group mothers receive experience questionnaire from kangaroo mother care and will compare. Bilirubin levels considered in newborns as the primary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506064617N12**

Registration date: **2015-09-16, 1394/06/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-16, 1394/06/25

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

2015-08-06, 1394/05/15

Expected recruitment end date

2015-11-06, 1394/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of kangaroo mother care on the level of bilirubin in the newborn after cesarean and maternal satisfaction from care after birth

Public title

Effects of kangaroo mother care on the level of bilirubin in the newborn after cesarean and maternal satisfaction from care after birth

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria newborns: infants born by cesarean delivery with spinal anesthesia; neonates (37 to 40 weeks of gestation); the apgar score birth fifth minute above 7. Inclusion criteria mothers: mothers of term infants; literate mothers; mothers are alert and awake; mothers receive spinal anesthesia. Exclusion criteria newborns: during the study, infants with respiratory distress or other problems; If, after the arrival newborn to the study inclusion criteria was not been observed; the newborn discharge during the study with parents satisfaction; pathologic jaundice factors (incompatibilities ABO-RH) or aggravating factors (deficiency glucose six phosphate dehydrogenase); cephalohematoma or significant contusion; respiratory distress syndrome or any condition that prevents of the delivery of newborn to mother; having a baby's skin disease; congenital anomalies; life-threatening problems; newborn alcohol syndrome. Exclusion criteria mothers: if the mothers does not want continued the study; after random selection of mothers in the control group was insisted to be in the intervention group; use psychotropic antidepressants, cigarette or other drugs; having previous experience of kangaroo mother care, study or employment mother in the field of medical sciences; mother's skin disease; having diabetes or hypertension; mother received general anesthesia.

Age

From **1 day** old to **5 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This study will done with random selection. Assigned acts to the mothers will be done in admission time with use of number opaque sealed envelopes.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Deputy of research, Tabriz University of Medical Sciences

Street address

Deputy of Research, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

Postal code

9775138947

Approval date

2015-07-06, 1394/04/15

Ethics committee reference number

TBZMED.REC.1394.342

Health conditions studied

1

Description of health condition studied

Kangaroo mother care

ICD-10 code

Z39.0

ICD-10 code description

Care and examination immediately after delivery

Primary outcomes

1

Description

The amount of bilirubin

Timepoint

Immediately after birth, 24 hours after birth, 36 hours after birth, 5 days after birth

Method of measurement

With using from Billy Check (K-J-8000 model, made in Chin)

Secondary outcomes

1

Description

Mothers satisfaction from care after birth

Timepoint

Mothers discharge day from hospital

Method of measurement

Questionnaire

2

Description

The mothers experience of kangaroo mother care

Timepoint

Mothers discharge day from hospital

Method of measurement

Questionnaire

Intervention groups

1

Description

The control group after mother exit of the operating room will be receive routine care in recovery room. Newborns baseline bilirubin will controlled through forehead skin after birth with Billy Check (K-J-8000 model, made in China). Twenty-four and thirty-six hours and fifth day after birth neonatal bilirubin will be control and recorded again. On the third day postpartum mothers' satisfaction will be measured through questionnaires

Category

Prevention

2

Description

The intervention group before mothers transfer to the operating room will be trained about kangaroo mother care for 30 minutes. Newborns baseline bilirubin will controlled through forehead skin after birth with Billy Check (K-J-8000 model, made in China). The this group babies will be placed between mother's breasts immediately after birth in the recovery room. With blanket will be kept warm and dry, and a hat will be placed on baby's head to prevent heat loss. Appropriate position will be given to mother with folding bed or pillows. Kangaroo mother care will continue for 30 minutes. This position will be continued time mother transfer to surgery ward. Kangaroo mother care will be continued in the ward after transfer three times a day, each time for 30 minutes at hours 7, 13 and 19 until discharge. Curtain will help to privacy during kangaroo mother care. The baby's bilirubin will be controlled with Billy Check from forehead skin at hours 24, 36 after birth and fifth day, and will be recorded. Two questionnaires will be giving to the mothers on the third day. Maternal satisfaction from postpartum care and their experiences of kangaroo care will be measured on the third day after birth

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatima Hospital

Full name of responsible person

Street address

Tabriz University of Medical Sciences

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of research, Tabriz University of Medical Sciences

Full name of responsible person

Doctor Rashidi

Street address

Deputy of Research, Tabriz University of Medical Sciences, Golgasht Street, 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

Seyyedrasooly Alehe

Position

Faculty member

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

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

Tabriz University of Medical Sciences

Full name of responsible person

Khiry Ziba

Position

Master student