Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Education based on Helping Babies Breathe Workshop Program for Midwives on the Neonatal asphyxia

Protocol summary

Study aim
Determining and comparing the percentage of neonatal with asphyxia before, during and after the intervention

Design
This study has two groups, including learners (midwives) who are trained and a group (asphyxiated infants) who measure the extent and severity of neonatal disease based on the performance of learners (midwives) and the sampling method is census.

Settings and conduct
The study was performed in Iran Hospital of Iranshahr University of Medical Sciences on the extent and severity of asphyxia in infants that The statistics of asphyxia neonates are recorded in three 6-month stages and the diagnosis is made based on clinical examination and the results of neonatal arterial blood samples.

Participants/Inclusion and exclusion criteria
Infants diagnosed with asphyxia according to the guideline will be included in the study.

Intervention groups
Students who obtain the required score of the questionnaire and OSCE after the workshop and are engaged in the delivery room, operating room and triage departments of the emergency department will be included in the study. Infants diagnosed with asphyxia according to the guideline will be included in the study.

Main outcome variables
AThe degree of asphyxia of infants and the Apgar score at birth of infants with asphyxia.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220211053998N1**
Registration date: **2022-03-02, 1400/12/11**
Registration timing: **registered_while_recruiting**
Last update: **2022-03-02, 1400/12/11**
Update count: **0**

Registration date
2022-03-02, 1400/12/11

Registrant information

Name
Ferdows Bameri

Name of organization / entity

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Iran (Islamic Republic of)

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+98 54 3721 1490

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bameriferdows@bums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-21, 1400/12/02

Expected recruitment end date
2023-08-24, 1402/06/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Education based on Helping Babies Breathe Workshop Program for Midwives on the Neonatal asphyxia

Public title
The Effect of Education based on Helping Babies Breathe Workshop Program for Midwives on the Neonatal asphyxia

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Infants with Apgar Scores less than 7 in the fifth minute of life Infants with a Potential Hydrogen(PH) less than 7 on umbilical Artery Blood Gas (ABG) Analysis in the first hour after Birth Infants with a Base excess (BE) less than -12 in Umbilical ABG Analysis in the first hour after Birth Diagnosis of Hypoxic Ischemic Encephalopathy (HIE) in the first 3 Days after Birth Multiple Organ Failure associated with HIE Birth Age more than 34 Weeks Born in Iran Hospital in Iranshahr

Exclusion criteria:

Genetic Syndromes or Congenital Anomalies of the Central Nervous System at Birth

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iranshahr University of Medical Sciences

Street address

No. 46, Imam Khomeini St., Iranshahr University of Medical Sciences

City

Iranshahr

Province

Sistan-va-Balouchestan

Postal code

9916643535

Approval date

2022-02-08, 1400/11/19

Ethics committee reference number

IR.IRSHUMS.REC.1400.019

Health conditions studied

1

Description of health condition studied

Asphyxia

ICD-10 code

R09.01

ICD-10 code description

Asphyxia

Primary outcomes

1

Description

Percentage of infants with asphyxia

Timepoint

Before intervention, during intervention, after intervention

Method of measurement

ABG test, Apgar score, clinical signs as determined by the treating physician or MRI

2

Description

Degrees of asphyxia in infants

Timepoint

Before intervention, during intervention, after intervention

Method of measurement

ABG test, Apgar score, clinical signs as determined by the treating physician or MRI

3

Description

Mean Apgar score of newborns

Timepoint

Before intervention, during intervention, after intervention

Method of measurement

Physical examination

Secondary outcomes

1

Description

The average score of midwives participating in the continuing education program to helping babies breathe in the workshop

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Questionnaire 18 questions to assess the knowledge and OSCE tests of the program to helping babies breathe

Intervention groups

1

Description

Intervention Group 1: Babies with asphyxia at birth: In this plan, in three consecutive periods of 6 months, the statistics of infants with asphyxia are collected according to the inclusion criteria (arterial blood test of the umbilical cord of newborns at birth, which is part of the hospital routine and neonatal Apgar score) in 6 months Second, midwives involved in birth, neonatal resuscitation program are trained and reminded 4 times according to a specific program, but in the first and third 6 months, no intervention is made in the field of midwifery education. Finally, the results and percentage of infants with asphyxia in these three time periods are compared and the effect of the outcome of continuing education is measured.

Category

Early detection

2

Description

Intervention Group 2: Midwives: In the second 6 months of collecting statistics on asphyxiated infants, at the beginning of the first, third, fifth and sixth months, all midwives involved in birth are taught in person in the form of a workshop, neonatal resuscitation program and the effect of continuing education on educational outcomes (Statistics of asphyxiated infants) is measured (statistics of infants with asphyxia in the first 6 months, second 6 months and third 6 months are compared).

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran hospital

Full name of responsible person

Ferdows Bameri

Street address

Iran Hospital, 4 km of Bampour Road

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nurse2012b.ferdows@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranshahr University of Medical Sciences

Full name of responsible person

Fatemeh Azarkish

Street address

No. 46, Imam Khomeini St., Iranshahr University of Medical Sciences

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Irshums@irshums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iranshahr University of Medical Sciences

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

Iranshahr University of Medical Sciences

Full name of responsible person

Ferdows Bameri

Position

Non-faculty nurse

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Iranshahr University of Medical Sciences

Full name of responsible person
Ferdows Bameri

Position
Non-faculty nurse

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

Name of organization / entity
Iranshahr University of Medical Sciences

Full name of responsible person
Ferdows Bameri

Position
Non-faculty nurse

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Master

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available