

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of the Helping Babies Survive program on Essential newborn care improvement in Beheshti Hospital affiliated to Isfahan University of Medical Sciences at 2019

Protocol summary

Study aim

Determination and Comparison of Relative Frequency of Temperature and Breathing Rate in 15-30-60 Minutes After Birth, Time of Clamping of the Baby Cord, Average Score of Infant Breastfeeding, at the End of First Hour, Average Score of Infant Breastfeeding, At the end of the first 24 hours in the control and intervention groups.

Design

The study has a control and intervention group with a sample size of at least 100.

Settings and conduct

Hospital staff will be trained in the infant survival program, and the ascetic will be trained before and after training, and then the lactation success checklist will be completed at the end of 1 hour and 24 hours of infants.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Parent consent to participate in the study - Newborn weighing more than 1500 g - Birth with normal vaginal delivery - Healthy newborn without congenital abnormalities and no delivery complications - No mental illness and addiction
Exclusion criteria: Maternal incidence of postpartum complications: thrombophlebitis, periodontal infection, pulmonary embolism, severe bleeding-hospitalization or neonatal death during the study

Intervention groups

In the control group, routine care is performed and in the intervention group, the care is based on the infant survival plan.

Main outcome variables

Evaluate the impact of implementing a newborn survival assistance program and selecting the appropriate program to improve basic neonatal care

General information

Reason for update

Acronym

خالی

IRCT registration information

IRCT registration number: **IRCT20191212045712N1**

Registration date: **2019-12-24, 1398/10/03**

Registration timing: **prospective**

Last update: **2019-12-24, 1398/10/03**

Update count: **0**

Registration date

2019-12-24, 1398/10/03

Registrant information

Name

najme ajoodanian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7576

Email address

n.ajoodanian@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the Helping Babies Survive program on Essential newborn care improvment in Beheshti Hospital affiliated to Isfahan University of Medical Sciences at 2019

IR.MUI.RESEARCH.REC.1398.411

Health conditions studied

1

Description of health condition studied

This study has no pathogenesis.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Improve basic baby care

Timepoint

Breastfeeding Success Checklist End of 1 Hour 24 Hours of Birth - Time of Cord Clamping During First Minutes of Birth - Temperature and Breathing at 15-30-60 Minutes

Method of measurement

Checklist-Stopwatch-Thermometer

Secondary outcomes

1

Description

The variable has no secondary consequence

Timepoint

The variable has no secondary consequence

Method of measurement

The variable has no secondary consequence

Intervention groups

1

Description

Intervention group: Intervention group: neonates born in maternity ward with trained personnel caring for infant survival program

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

This study has no pathogenesis

Full name of responsible person

The Najam of the Adudians

Street address

Isfahan School of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran

City

Esfahan

Province

Public title

The effect of the Helping Babies Survive program on Essential newborn care improvment

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Infants weighing over 1500 grams

Exclusion criteria:

Babies weighing less than 1500 grams

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)

Randomized

Randomization description

Randomized control

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

sofe Blvd Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673465

Approval date

2019-11-02, 1398/08/11

Ethics committee reference number

Isfahan
Postal code
8174673465
Phone
+98 31 3771 4664
Email
n.ajoodanian@nm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
shaghayegh hagh joy gavanmard
Street address
Esfahan
City
Esfahan
Province
Isfahan
Postal code
8174673465
Phone
+98 31 3771 4664
Email
n.ajoodanian@nm.mui.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
The Skull of the Adudians
Position
Clinical Faculty
Latest degree
Master
Other areas of specialty/work
Nursery
Street address

Faculty of Nursing and Midwifery, School of Nursing
and Midwifery, Isfahan University of Medical Sciences,
Isfahan, Iran

City

Esfahan

Province

Isfahan

Postal code

8174673465

Phone

+98 31 3771 4664

Email

n.ajoodanian@nm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
The Najmeh ajoodanian
Position
Clinical Faculty
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Faculty of Nursing and Midwifery, School of Nursing
and Midwifery, Isfahan University of Medical Sciences,
Isfahan, Iran
City
Esfahan
Province
Isfahan
Postal code
8174673465
Phone
+98 31 3771 4664
Email
n.ajoodanian@mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
The Najam of the Adudians
Position
Clinical Faculty
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Faculty of Nursing and Midwifery, School of Nursing
and Midwifery, Isfahan University of Medical Sciences,
Isfahan, Iran
City
Esfahan

Province
Isfahan
Postal code
8176673465
Phone
+98 31 3771 4664
Email
n.ajoodanian@mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

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

Title and more details about the data/document

Breastfeeding success checklist is shareable after coding.

When the data will become available and for how long

Starting data access period 6 months after printing

To whom data/document is available

The data is accessible to staff at academic institutions

Under which criteria data/document could be used

In order to eliminate ambiguities in choosing the right program

From where data/document is obtainable

Anyone can access the documentation at this email
n.ajoodanian@mui.ac.ir

What processes are involved for a request to access data/document

Documents will be sent within two months after the request is received by email and review of the request.

Comments