

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 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 for maternal and neonatal study: 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 improvement in Beheshti Hospital affiliated to Isfahan University of Medical Sciences at 2019

IR.MUI.RESEARCH.REC.1398.411

#### Public title

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

#### 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

### 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

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**  
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**Phone**  
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**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 Aduadians  
**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

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#### Postal code

8174673465

#### Phone

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#### Email

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
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The Najmeh ajoodanian  
**Position**  
Clinical Faculty  
**Latest degree**  
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Faculty of Nursing and Midwifery, School of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran  
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**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 Aduadians  
**Position**  
Clinical Faculty  
**Latest degree**  
Master  
**Other areas of specialty/work**  
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**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**