

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Impact of empowerment program on participation and attachment of parents with premature infants admitted to neonatal intensive care unit of Sayyad Shirazi Hospital in Gorgan in 1397

#### Protocol summary

##### Study aim

Impact of Breast Immunization Program on Premature Infant

##### Design

The experimental group was a premature infant, admitted in the intensive care unit of Sayyad Shirazi Hospital. The nurses are randomly selected and the intervention and control groups are divided by coin throwing. The total number is 50 . The trial is a type of clinical trial.

##### Settings and conduct

The place of intervention of the intensive care unit of Sayyad Shirazi Hospital in Gorgan is done by clinical trial. The samples are divided into test and control groups. First, pre test intervention is taken. On the fourth day of admission to the intervention group, the first stage of self-remittance is implemented. Four days later, the implementation of the first stage, the second stage of implementation, is taken in the field of participation in the pre-test. Two days prior to discharge, the test pre-test is also done for attachment.

##### Participants/Inclusion and exclusion criteria

Reading and writing literacy and aged 18+. It is directly responsible for the care of the patient. Parents do not have physical and mental disabilities. Premature infants with a baby's age have no problem and no malformations. 26 to 34 weeks and birth weight less than 2500 grams. If they do not want to continue their collaboration, they will be excluded from the study. Two absentee sessions eliminate parents from studying.

##### Intervention groups

The intervention is carried out in an empowering program and providing information on premature infants in order to increase participation and attachment and increase compliance with the critical situation in the intervention and control group.

##### Main outcome variables

Parental compatibility with existing conditions Parent company in baby care An attachment to the premature baby was born Take advantage of your potential abilities

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170512033932N6**

Registration date: **2019-01-06, 1397/10/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-01-06, 1397/10/16**

Update count: **0**

##### Registration date

2019-01-06, 1397/10/16

##### Registrant information

##### Name

Hosein Motahariniya

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3222 4908

##### Email address

h\_hojjati@aliabadiu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-02, 1397/07/10

##### Expected recruitment end date

2019-06-21, 1398/03/31

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Impact of empowerment program on participation and attachment of parents with premature infants admitted to neonatal intensive care unit of Sayyad Shirazi Hospital in Gorgan in 1397

**Public title**

An Empowerment Program on Parents with Preterm Infants

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Get informed consent from the company in this study.. Reading and writing materials are over 18 years old . It is the direct responsibility of caring for the patient. Waldin is not physically and mentally handicapped Premature infants admitted at age 26 to 34 weeks and birth weight less than 2500 grams.

**Exclusion criteria:**

If they do not want to continue their collaboration, they will be excluded from the study Two absentee sessions eliminate parents from studying

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A simple randomization is done with sealed envelope tools in such a way that the envelopes are written in letters A and B, and the mothers are asked to select an envelope that the group A of the intervention group and the B group will be tested.

**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 Golestan University of Medical Sciences

**Street address**

Gorgan, Golshahr Square, Golshahr 32, Gorgan

**City**

Gorgon

**Province**

Golestan

**Postal code**

1234

**Approval date**

2018-08-27, 1397/06/05

**Ethics committee reference number**

IR.GOUMS.REC.1397.092

**Health conditions studied****1****Description of health condition studied**

In this study, the effect of parents empowerment on their participation in care and their attachment level is studied

**ICD-10 code**

ICD-10 Cha

**ICD-10 code description**

عوامل مؤثر بر سلامت و تماس با خدمات بهداشتی و درمانی

**Primary outcomes****1****Description**

Parents have premature infants

**Timepoint**

Before intervention, 4.8 days after intervention and 2 days before discharge

**Method of measurement**

Avant Attachment Questionnaire and Participation Questionnaire for Parents with Premature Infants

**Secondary outcomes**

empty

**Intervention groups****1****Description**

ntervention group: Includes 25 parents with premature infants. After receiving the pre-test, the demographic characteristics, attachment and participation of the parents in the 2-4 days after the admission and 4-4 days after the first stage receive the necessary training for the newborns, and 2 days before the post-discharge post-attachment test And participate.

**Category**

Behavior

## 2

### Description

Control group: Twenty-five parents with premature infants admitted to the neonatal intensive care unit, on the second day of admission, pre-test, demographic characteristics, attachment and participation were taken without intervention. Two days before the discharge, the post-test was also taken

### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Sayyad Shirazi Hospital

**Full name of responsible person**

Hanieh Sajadi

**Street address**

Golshahr Square, Golshahr Street 32

**City**

Gorgan

**Province**

Golestan

**Postal code**

1234

**Phone**

+98 17 3322 3131

**Email**

H\_hojjati@aliabadiu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Rouhollah Samii

**Street address**

Azad University Street, Azad University of Aliabad

**City**

Ali Abad

**Province**

Golestan

**Postal code**

1234

**Phone**

+98 17 3323 3131

**Email**

H\_hojjati@aliabadiu.ac.ir

**Grant name**

2000000

**Grant code / Reference number**

1234

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

Yes

**Title of funding source**

Islamic Azad University

**Proportion provided by this source**

1

**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**

Persons

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Islamic Azad University of Ali Abad Katoul

**Full name of responsible person**

Hanieh Sajadi

**Position**

Nures

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Golshahr Square, Golshahr Street 32

**City**

Gorgan

**Province**

Golestan

**Postal code**

1234

**Phone**

+98 17 3323 3131

**Email**

H\_hojjati@aliabadiu.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Hanieh Sajadi

**Position**

Nures

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Golshahr Square, Golshahr Street 32

**City**

Gorgan

**Province**

Golestan

**Postal code**

1234

**Phone**

+98 17 3323 3131

**Email**

H\_hojjati@aliabadiu.ac.ir

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

Islamic Azad University

**Full name of responsible person**

Golbahar Akhondzadeh

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Mudsar-Golshahr-Golshahr Square 32

**City**

Gorgan

**Province**

Golestan

**Postal code**

1234

**Phone**

+98 17 3323 3131

**Email**

G\_akhoondzadeh@yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Results and results of the study will be shared

**When the data will become available and for how long**

Post-print information will be publicly available

**To whom data/document is available**

All students and researchers can apply for information.

**Under which criteria data/document could be used**

Use of questionnaires and titles for further studies and studies is allowed.

**From where data/document is obtainable**

Email haniehsajadi74@gmail.com Message to be sent.

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

Email request or contact

**Comments**