Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

“Designing a Neurodevelopmental care Interventional package of Preterm infants in NICU (from birth to 1 month corrected age) for parents and determining its effectiveness on developmental outcomes in infancy”

Protocol summary

Study aim

Prematurity is one of the major causes of developmental delay, and parent education and intervention can be effective in reducing the developmental delay of these infants at a time. This study aimed to design a neuro-evolving interventional package for the preterm infants for parents in Iran. Design And its effectiveness in assessing the evolutionary outcomes of the childhood period. This study is a randomized cluster randomized clinical trial, initially based on the review of available resources, the content of the intervention packet will be based on evidence. Finally, the strategies for implementation and implementation of the package will be identified with the views of the experts and the parents. In the second stage, the effectiveness of the "interventional package of neuro-neurological-neonatal care for the parents of the premature newborns will be investigated on evolutionary implications in infancy. Entry into a study in which their babies are admitted to the NICU. Subsequently, interventional interventions for the parents of the intervention group during the hospitalization period will be implemented in the hospital, and will be closed to the same observation group with the same number of pages with the design It will be similar to the original package that includes the routine tutorial package After that, at the end of one month of modulation, using the Bailey (III) test, then the modified results will be evaluated with the age and procedure questionnaire (ASQ)

Design

Community-based

Settings and conduct

Millad Hospital Rasol Akram Hospital Ali Askhar Hospital

Participants/Inclusion and exclusion criteria

Preterm infants in NICU

Intervention groups

Preterm infants in NICU

Main outcome variables

Designing a Neurodevelopmental care Interventional package for Preterm infants Short-term outcomes after extreme preterm birth Developmental Outcome of Premature Infants

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180125038502N1**
Registration date: **2018-01-30, 1396/11/10**
Registration timing: **prospective**

Last update: **2018-01-30, 1396/11/10**
Update count: **0**

Registration date

2018-01-30, 1396/11/10

Registrant information

Name

Fatemeh Fallah Rostami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2218 0099

Email address

fat.rostami@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-06, 1396/12/15

Expected recruitment end date

2018-08-06, 1397/05/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
"Designing a Neurodevelopmental care Interventional package of Preterm infants in NICU (from birth to 1 month corrected age) for parents and determining its effectiveness on developmental outcomes in infancy"

Public title
"Designing a Neurodevelopmental care Interventional package of Preterm infants in NICU (from birth to 1 month corrected age) for parents and determining its effectiveness on developmental outcomes in infancy"
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Preterm infants in NICU
Exclusion criteria:
Age
From **196 days** old to **238 days** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Mothers and evaluators of the outcomes and analysis of data about the grouping of samples will be blind . To avoid contamination of information, time and space blocks are used.
Placebo
Used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee ofUniversity of Social Welfare and Rehabilitation Sciences
Street address
University of Social Welfare and Rehabilitation Sciences.Kodakyar St.Velenjak Blvd.Tehran.Iran
City
Tehran
Province
Tehran
Postal code
۱۹۸۵۷۱۳۸۳۴
Approval date
2017-11-06, 1396/08/15
Ethics committee reference number
IR.USWR.REC.1396.252

Health conditions studied

1

Description of health condition studied
Designing a Neurodevelopmental care Interventional package
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Designing a Neurodevelopmental care Interventional package of Preterm infants
Timepoint
Before the intervention begins
Method of measurement
Content validity ratio and content validity index

2

Description
Developmental Outcome of Premature Infants
Timepoint
in the 4 month and 6 month
Method of measurement
Ages and stages questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The status of newborns at the beginning of the study was determined by using

variables: gender, type of delivery, type of pregnancy, occupation and parental education, place of residence, history of failure in the family, number of variables, head circumference, height of the baby during birth, breast size at birth, The Apgar score of minutes 1 and 5, gestational age, and maternal age will be assessed. For pre-test, Ballard's new test is used in two groups. Then, an intervention pack will be implemented for the intervention group's parents during the hospitalization periods phone number for contacting a researcher will also be provided to parents to contact you if needed. Supervising the implementation of the evolutionary care package will be done by the researcher and guidance in the neonatal intensive care unit. Afterwards, in 4 and 6 months, the consequences will be evaluated with the ASQ tool.

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Milad Hospital
Full name of responsible person
Fatemeh fallah rostami
Street address
Millad tower,Haki, highway,Tehran
City
Tehran
Province
Tehran
Postal code
1449614531
Phone
+98 21 84090
Email
fallah.rostami@yahoo.com
Web page address
http://www.miladhospital.com

2

Recruitment center
Name of recruitment center
Rasoul Akram Hospital
Full name of responsible person
Fatemeh Fallah Rostami
Street address
Tehran,Iran
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6655 8811
Email
fallah.rostami@yahoo.com

3

Recruitment center
Name of recruitment center
Ali Asghar Children's Hospital
Full name of responsible person
Fatemeh Fallah Rostami
Street address
Zafar St,Tehran
City
Tehran
Province
Tehran
Postal code
۵۶۱۳۶۴۳۱۹۷
Phone
+98 21 2222 2041
Email
fallah.rostami@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Fatemeh Fallah Rostami
Street address
University of Social Welfare and Rehabilitation Sciences.Kodakyar St.Velenjak Blvd.Tehran.Iran
City
Tehran
Province
Tehran
Postal code
1985713834
Phone
+98 21 2218 0099
Email
fallah.rostami@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences

Full name of responsible person
Fatemeh Fallah Rostami

Position
Candidate PHD student

Latest degree
Ph.D.

Other areas of specialty/work
Neuroscience

Street address
Tehran,Iran

City
Tehran

Province
Tehran

Postal code
1985713834

Phone
+98 21 2218 0099

Email
fallah.rostami@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Fatemeh Fallah Rostami

Position
Candidate PhD Student

Latest degree
Ph.D.

Other areas of specialty/work
Neuroscience

Street address
Tehran

City
Tehran

Province
Tehran

Postal code
1985713834

Phone
+98 21 2218 0099

Email
fallah.rostami@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Fatemeh Fallah Rostami

Position
Candidate PhD Student

Latest degree
Ph.D.

Other areas of specialty/work
Neuroscience

Street address
Tehran,Iran

City
Tehran

Province
Tehran

Postal code
1985713834

Phone
+98 21 2218 0099

Email
fallah.rostami@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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Yes

When the data will become available and for how long
Yes

To whom data/document is available
Yes

Under which criteria data/document could be used
Yes

From where data/document is obtainable
Yes

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

Comments
Yes