

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Investigating the effect of ultrasonic hemodynamic monitoring by nurses on early detection of changes in hemodynamic and physical indicators of neonates and its stabilization

Protocol summary

Study aim

Determining the effect of ultrasonic hemodynamic monitoring by nurses on early detection of changes in hemodynamic and physical indicators of premature neonates and its stabilization

Design

The clinical trial has a group that is examined before and after the intervention. Single, unblinded, non-random and without a study phase on 50 patients.

Settings and conduct

The present study will be conducted as a semi-experimental clinical trial in VALIASR Hospital of Imam Khomeini Hospital Complex in Tehran. The target population in this study will be 24 to 37-week-old neonates hospitalized in the neonatal intensive care unit. Sampling will be done among premature neonates treated by Dr. Dalili and according to the inclusion criteria. The researcher will visit the neonatal intensive care unit of Imam Khomeini Hospital every day in the morning shifts. First, all the vital signs are checked and recorded, then under the supervision of Dr. Dalili, the USCOM device will be used for the samples. After registering the parameters, different therapeutic interventions will be performed in order to diagnose and treat the neonates in time

Participants/Inclusion and exclusion criteria

24 to 37 weeks premature neonates; Informed and written consent of parents for their neonate's participation in the research

Intervention groups

The intervention in this research is the use of ultrasonic cardiac output monitoring (USCOM) device on 24 to 37 weeks neonates. According to the parameters given by the device (which are several hemodynamic parameters), appropriate treatment and intervention methods such as positioning, fluid therapy, etc. are performed on them

Main outcome variables

The main result of this study is the early detection of hemodynamic disorders in neonates, which leads to faster treatment, better weighing of the neonates, and faster discharge from the hospital.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220831055840N1**

Registration date: **2023-05-12, 1402/02/22**

Registration timing: **prospective**

Last update: **2024-12-06, 1403/09/16**

Update count: **1**

Registration date

2023-05-12, 1402/02/22

Registrant information

Name

Shahrzad Yaseri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8843 8521

Email address

shahrzadyaseri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-05, 1402/03/15

Expected recruitment end date

2023-07-24, 1402/05/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of ultrasonic hemodynamic monitoring by nurses on early detection of changes in hemodynamic and physical indicators of neonates and its stabilization

Public title

Investigating the effect of ultrasonic hemodynamic monitoring on early detection of changes in hemodynamic and physical indicators of neonates and its stabilization

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

24 to 37 weeks premature neonates Informed and written consent of parents for their neonate's participation in the research

Exclusion criteria:

Parents unwillingness to continue participating in the study Morbidity or death of neonates Having emphysema

AgeFrom **1 day** old to **28 days** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **50****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 Tehran's imam khomeini Hospital

Street address

First Floor., No. 72, Soraya Alley., Adibi street.,

Shariati street

City

Tehran

Province

Tehran

Postal code

1613633581

Approval date

2022-12-28, 1401/10/07

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.254

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

Hemodynamic Disorders of Neonates

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Percentage of neonates with changes in hemodynamic indicators

Timepoint

At the beginning of the study and six weeks after the start of the intervention

Method of measurement

The monitoring device of the company Poindangan Rah Saadat and the ultrasonic monitoring device of cardiac output

2**Description**

Percentage of neonates with changes in physical indicators

Timepoint

At the beginning of the study and six weeks after the start of the intervention

Method of measurement

Scales of Seka

Secondary outcomes

empty

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

Intervention group: The intervention is performed on neonates aged 24 to 37 weeks. First, their monitoring is done and recorded by the monitoring device of the company Poyandegan Rah Saadat, and then the ultrasonic cardiac output monitoring device is used to

check and record the changes in the hemodynamic and physical indicators of the newborns. If needed, interventions such as drug therapy, fluid therapy, position change, and oxygen therapy will be performed by the relevant doctor, and these interventions will continue until the baby's condition stabilizes

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Shahrzad Yaseri

Street address

second floor, neonatal special care department, Valiasr complex,, Imam Khomeini Hospital Complex, Dr. Gharib Street, the end of Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

+98 21 6658 1420

Email

Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Jamaluddin Bagjani

Street address

1st building, 3rd floor, Faculty of Nursing and Midwifery, Dr. Mirkhani St., (Nusrat East), Toheed Square

City

Tehran

Province

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Postal code

1419733171

Phone

+98 21 6692 4411

Email

Higher_education@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Shahrzad Yaseri

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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N072, Soraya Alley, Adibi Street ,Shariati Street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahrzad Yaseri

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD

Trial results

Please tick if results have been published

Yes

Summary result posting date
2024-12-06, 1403/09/16

Table of baseline comparison
Participant flow diagram

Obtaining the approval of the research plan by the ethics committee and obtaining permission from the joint organizational ethics committee of the Faculty of Nursing and Midwifery, Tehran University of Medical Sciences.

Refer to the neonatal intensive care unit of Waliasr hospital and introduce yourself to the relevant authorities and families participating in the study .

Obtaining informed consent from the parents of infants participating in the study and explaining the objectives of the study Selection of samples according to the inclusion criteria

Table of variable outcomes' results
Table of adverse events
First publication date
empty

Due to the confidentiality of the information, there is no decision to publish the data file

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

No - There is not 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

The data includes premature babies who were hospitalized under the supervision of 2 doctors. Personal information cannot be published due to confidentiality and lack of parental permission. But the consequences and results are shared

When the data will become available and for how long

Beginning of the access period from 1404

To whom data/document is available

Only researchers working in academic and scientific institutions can request access to study documents

Under which criteria data/document could be used

The necessary condition for sending the request depends on sending the email at the same time as the need to use the information

From where data/document is obtainable

To get the data, call 09001166090 or email Shahrzadyaseri@gmail.com

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

First, the request is sent, then it is checked by the reviewer and the main researcher The response time is between 2 weeks and 1 month

Comments

Abstract of published paper