

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effect of care program training in children with coronary artery on nurses' clinical competence and disease severity

Protocol summary

Study aim

Determining the effect of designed care program in children with coronary heart disease on the clinical competence of nurses and the severity of the disease in the pediatric intensive care unit of Akbar Mashhad Hospital

Design

The control trial is parallel to the control group. In one group of patients, they receive routine nursing care, and in another group, they receive nursing care in accordance with the care package designed by trained nurses. In each group, 22 patients and a total of 44 patients will be included in the study.

Settings and conduct

In this study, the control group receives routine nursing care based on experience, etc., and the intervention group receives guided care based on a standardized care package according to specific problems in the clinic. Blinding is not performed and the patient, The researcher, nurses, physician in charge of the patient's treatment and the statistical analyst know in which group they are. The study will be performed at the PICU of Akbar Hospital in Mashhad.

Participants/Inclusion and exclusion criteria

Children whose RT-PCR test is positive. Age between 0 and 18 years. They are hospitalized in the intensive care unit. Patients who do not want to continue participating in the study or have been discharged before the 6th day of hospitalization have been excluded from the study. Nurses working in the PICU of Akbar Hospital.

Intervention groups

Intervention group: will receive clinical care based on a care package designed with standard nursing diagnoses based on print sources of Linda and Dwayne Jazz nursing diagnoses. Control group: will only receive routine ward care. Improving the clinical competence of nurses in accordance with the training is the basis for the implementation of the care package.

Main outcome variables

ICU admission, death, and disease severity, clinical qualification

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210703051773N1**

Registration date: **2022-02-22, 1400/12/03**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-22, 1400/12/03**

Update count: **0**

Registration date

2022-02-22, 1400/12/03

Registrant information

Name

Samaneh Arteshidar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3273 2089

Email address

arteshidars982@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of care program training in children with coronary artery on nurses' clinical competence and disease severity

Public title

Evaluation of implementation of care package in children with coronary artery on nurses' clinical competence and disease severity .

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Covid disease 19 based on the diagnosis of the treating physician Admission to the intensive care unit
Satisfaction with participation in the study

Exclusion criteria:

Eluctance to continue participating in the study They have early discharge

AgeFrom **1 month** old to **18 years** old**Gender**

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **44****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

In this study, the effect of education in two groups of nurses working in the ward and children with Covid 19 is measured.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

Street address

Mashhad, Ibn Sina St., towards Imam Reza Hospital, School of Nursing and Midwifery

City

Mashhad

Province

Razavi Khorasan

Postal code

9771946155

Approval date

2021-08-15, 1400/05/24

Ethics committee reference number

IR.MUMS.NURSE.REC.1400.045

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

Covid-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

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

Clinical competence of nurses working in pediatric wards

Timepoint

In nurses before and after the workshop.

Method of measurement

Clinical Competency Questionnaire in Nurses

2**Description**

Disease severity score

Timepoint

At the time of admission on the third and sixth day of admission to the intensive care unit.

Method of measurement

PRISM III disease severity assessment form

Secondary outcomes

empty

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

Intervention group: Receiving clinical care based on a care package designed from the day of hospitalization to the sixth day of hospitalization or until the day of discharge. 19 children. In the process of designing this package, first the files of patients with Covid 19 will be studied and analyzed. The list of problems in Covid children will be extracted based on regional data and a diagram for each of the problems in these children. Evidence-based nursing care flowchart will be set. To implement this intervention in the form of care package,

first in a 3-day workshop and 3 hours every day, this care package will be taught to nurses working in the care of 19 children. Then, using a check Relevant lists, the process of implementing these cares is followed in the clinic. The intervention group is the patients who will receive the above cares. It should be noted that in the period when we are collecting the care package, the data of the control group will be collected and as soon as the package is prepared and its validity is determined, the care package will be implemented. Those who received care under the above care package (intervention group) will be compared with children with Covid 19 who were not cared for under the above care package (control group).

Category

Rehabilitation

2

Description

Control group: Children with Covid 19 who are not designed according to the care package or the above protocol.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Children's Hospital

Full name of responsible person

Aramesh Rezaian

Street address

Mashhad, Ibn Sina St., towards Imam Reza Hospital,
School of Nursing and Midwifery

City

Mashhad

Province

Razavi Khorasan

Postal code

9771946155

Phone

+98 56 3272 2089

Email

Arteshidars982@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Aramesh Rezaian

Street address

Mashhad, Ibn Sina St., towards Imam Reza Hospital,
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Province

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Arteshidars982@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Aramesh Rezaian

Position

science Committee

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Mashhad, Ibn Sina St., towards Imam Reza Hospital,
School of Nursing and Midwifery

City

Mashhad

Province

Razavi Khorasan

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City

Mashhad

Province

Razavi Khorasan

Postal code

9717946155

Phone

+98 56 3272 2089

Email

Arteshidars982@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Aramesh Rezaian

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School of Nursing and Midwifery

City

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Province

South Khorasan

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Email

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

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

Part of the data, such as information about the main outcome, can be shared.

When the data will become available and for how long

6 months after printing

To whom data/document is available

Academic and scientific institutions

Under which criteria data/document could be used

People that the university allows access to.

From where data/document is obtainable

Mashhad University of Medical Sciences. School of Nursing and Midwifery Ms. Aramesh Rezaeian
RezaeianA@mums.ac.ir Ms. Samaneh Arteshidar
Arteshidars982@mums.ac.ir

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

Contact with the project manager and after coordination with the School of Nursing and Midwifery, data will be provided.

Comments