Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation of therapeutic outcome of ringer lactate in treatment of acute resuscitation phase of severe dehydration children a randomized clinical trial

Protocol summary

Study aim

Comparison of the time for the disappearance of symptoms of severe dehydration and the time for correction of acidosis in two groups receiving normal saline and Ringer's lactate.

Design

A clinical trial with the control group, triple blinded, randomized, phase 3, on 104 patients. The random Allocation software is used for randomization.

Settings and conduct

This is a randomized controlled clinical trial that will be conducted in Rasht 17 Shahrivar Hospital in 1402 on children referred to the emergency department due to severe dehydration caused by acute diarrhea. The sampling method of this study is consecutive.

Participants/Inclusion and exclusion criteria

inclusion criteria: Age between 30 days and 14 years Severe dehydration Exclusion criteria: Severe acute malnutrition, duration of diarrhea more than 7 days, presence of blood in stool, underlying systemic disease, receiving outpatient Ringer's serum or normal saline in the last 24 hours, electrolyte disorder such as hypo or hypernatremia in the patient's initial tests, seizures in the course Hospitalization

Intervention groups

Intervention group: 20 cc of Ringer's serum lactate will be injected intravenously as a bolus liquid per kilogram of weight. After initial resuscitation, patients were treated with dextrose saline serum as a maintenance fluid. Control group: 20 cc of normal saline fluid per kilogram of body weight will be administered through the peripheral vein as a bolus liquid, and if there is no improvement in the signs and symptoms of dehydration, the second and third dose of normal saline will be administered with the same dose.

Main outcome variables

Primary outcome: Time to exit from severe dehydration

Secondary outcome: Time to resolve acidosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210201050199N2**
Registration date: **2023-08-26, 1402/06/04**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-26, 1402/06/04**
Update count: **0**

Registration date

2023-08-26, 1402/06/04

Registrant information

Name

manijeh Tabrizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 9002

Email address

drs.tabrizi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of therapeutic outcome of ringer lactate in treatment of acute resuscitation phase of severe dehydration children a randomized clinical trial

Public title
Evaluation of therapeutic outcome of ringer lactate in treatment of acute resuscitation phase of severe dehydration children a randomized clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Severe dehydration Age 30 days to 14 years
Exclusion criteria:
Severe and acute malnutrition Duration of diarrhea more than 7 days The presence of blood in the stool underlying systemic disease Receiving Ringer's serum or normal saline in the last 24 hours Electrolyte disorder such as hypo or hypernatremia in the initial tests of the patient Occurrence of seizures during hospitalization

Age
From **30 days** old to **14 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **104**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly divided into two groups of 52 people. The sampling method of this study is in the form of gradual sampling (consequential sampling). Thus, according to the referrals of children to 17 Shahrivar Hospital with complaints of diarrhea and having entry criteria, they are placed in groups A (Ringer's Lactate) and B (Normal Saline). The method of allocating children in the two respective groups is based on quadruple random blocks, and the sequence of selecting the samples will be done through the Random Allocation software. The varnished and sealed letter is kept hidden. After reading the list, the children will be placed in two groups A and B based on the sequence of this list.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this triple-blind study, the patient and the researcher were blind regarding the use of unlabeled serums which were titled A and B. Also, the data analyst will be blind to the assigned groups and analyze data as A and B. Notably. the label of the serum type was removed by a non-collaborating nurse in the plan and identified as groups A and B.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of the vice chancellor of Guilan University of Medical Sciences

Street address
Siadati

City
rasht

Province
Guilan

Postal code
4144444444

Approval date
2023-07-12, 1402/04/21

Ethics committee reference number
IR.GUMS.REC.1402.234

Health conditions studied

1

Description of health condition studied
Dehydration

ICD-10 code
X54

ICD-10 code description
Lack of water

Primary outcomes

1

Description
Primary outcome: comparison of the time for the disappearance of symptoms of severe dehydration

Timepoint
At the beginning and six hours after the start of treatment

Method of measurement
Clinical examination

Secondary outcomes

1

Description

Time to resolve acidosis

Timepoint

At the beginning and six hours after the start of treatment

Method of measurement

blood test

Intervention groups

1

Description

Intervention group: 20 cc of Ringer's serum lactate will be injected intravenously as a bolus liquid per kilogram of weight. After initial resuscitation, patients were treated with dextrose saline serum as a maintenance fluid.

Category

Treatment - Other

2

Description

Control group: 20 cc of normal saline fluid per kilogram of body weight will be administered through the peripheral vein as a bolus liquid, and if there is no improvement in the signs and symptoms of dehydration, the second and third dose of normal saline will be administered with the same dose.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

17 Shahrivar Children's Hospital

Full name of responsible person

Manijeh Tabrizi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammadreza Naghipour

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Manijeh Tabrizi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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inquiries

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Person responsible for updating data

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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
Ethical issues
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable