

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A comparison between the simultaneous consumption of Oral Rehydration Solution (ORS) along with rice soup and consuming ORS per se in the treatment of acute diarrhea in 6-24 months old children

Protocol summary

Summary

Objectives: This study will compare the simultaneous consumption of Oral Rehydration Solution (ORS) along with rice soup and consuming ORS per se in the treatment of acute diarrhea in 6-24 months old children.

Methods: This single blind clinical trial research will be carried out on 40 patients with acute watery diarrhea in the age range of 6-24 months. The patients' diarrhea onset should not exceed 72 hours and they will be hospitalized at the "the 22nd of Bahman Hospital" in Gonabad, Iran. We will obtain the parents' written consent for participation of their children. These children will be randomly assigned into two groups using the Table of Random Numbers. To ensure the sample equality in the two groups, we will employ Balanced Blocking Randomization (BBR) method using four cell blocks. The patients do not know to which group they will be assigned (intervention or control group). The patients in control group will receive ORS for treating diarrhea using the dose recommended by the World Health Organization (WHO); and the patients in intervention group, in addition to ORS, will receive 100 cc of rice soup for those who were one year old or higher and 50 cc for those who were less than one year for every time of excretion. The soup will contain 100 g of Iranian rice, 6 g of table salt, and 1.2 liter of distilled water. The blended rice will be boiled over a gas burner with continuous stirring until the final volume reaches 1 L. Exclusion criteria include: severe vomiting along with diarrhea and the parents' unwillingness to continue the study. Information on background variables, frequency of diarrhea, improvement of diarrhea, and laboratory variables will be recorded in the checklists and then the data will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310169459N1**
Registration date: **2014-01-07, 1392/10/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-07, 1392/10/17

Registrant information

Name

Mojtaba Kianmehr

Name of organization / entity

Gonabad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 53 3722 3028

Email address

kianmehr.m@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Gonabad University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between the simultaneous consumption of Oral Rehydration Solution (ORS) along with rice soup and consuming ORS per se in the treatment of acute diarrhea in 6-24 months old children

Public title

The effect of rice soup in treatment of acute diarrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: •Children between the ages of 6 and 24 months •Underlying disease may not be the cause of diarrhea. •More than 72 hours from the onset of diarrhea is passed. •The amount of serum sodium and potassium ions is in the normal range. •The patient does not consume the foods such as syrup, artificial ingredients, very sweet food, fruit juice, yogurt, butter milk, etc. that increase or decrease the severity of diarrhea. •The patient should continue with the diet. Exclusion criteria: • Regarding medicine, continuing the research is not possible for the patient. •The patient's parents are not willing to continue the investigation. •If the patient abandons the required diet during the dietary intervention. •If there is severe vomiting along with diarrhea.

Age

From **6 years** old to **24 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

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

Single 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 Gonabad University of Medical

Sciences

Street address

Vice chancellor for research, Gonabad University of Medical Sciences, Next to the Asian Road

City

Gonabad

Postal code

9691793718

Approval date

2012-04-10, 1391/01/22

Ethics committee reference number

91/1/4 / 51

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

Acute Diarrhea

ICD-10 code

K59.1

ICD-10 code description

functional diarrhea

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

The use rate of ORS solution

Timepoint

The first 24 hours, the second 24 hours, and the third 24 hours

Method of measurement

Determination of consumed volume by graded container

2**Description**

The use rate of intravenous fluids

Timepoint

The first 24 hours, the second 24 hours, and the third 24 hours

Method of measurement

Observation

3**Description**

Serum levels of Na and K ions

Timepoint

The onset of hospitalization, before any kind of intervention

Method of measurement

Blood collection and its experimenting with flame photometer

4**Description**

Serum levels of Urea

Timepoint

The onset of hospitalization, before any kind of intervention and at the end of intervention, before discharge

Method of measurement

Blood collection and its experimenting through spectrophotometer

Secondary outcomes

1

Description

Hospitalization stay

Timepoint

The end of intervention

Method of measurement

Observation

Intervention groups

1

Description

Intervention 1 in the control group: the patients in this group will receive ORS (produced by Hayan company, Iran) for treating diarrhea using the treatment recommended by WHO based on which the required amount of both intravenous injections and ORS has been determined.

Category

Treatment - Other

2

Description

Intervention 2 in the intervention group: the patients in this group, in addition to ORS (produced by Hayan company, Iran), will receive rice soup till their dismissal from the hospital based on the treatment recommended for diarrhea by WHO. The soup will be 100 cc for those who are one year old or higher and 50 cc for those who are less than one year old for every time of excretion. In this regard, we will decrease the amount of ORS so that it will not exceed the allowed amount received by the patient. The soup will contain 100 g of Iranian rice, 6 g of table salt, and 1.2 liter of distilled water. The blended rice will be boiled over a gas burner with continuous stirring until the final volume reaches 1 L.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

the 22nd of Bahman Hospital, Gonabad University of Medical Sciences

Full name of responsible person

Jalil Moshari

Street address

the 22nd of Bahman Hospital, Naser Khosro St.

City

Gonabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Gonabad University of Medical Sciences

Full name of responsible person

Ali Ekrami

Street address

Vice chancellor for research, Gonabad University of Medical Sciences, Next to the Asian Road

City

Gonabad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Gonabad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Mojtaba Kianmehr

Position

PhD in Biophysics / Assistant Professor

Other areas of specialty/work

Street address

Gonabad University of Medical Sciences, Next to the Asian Road

City

Gonabad

Postal code

9691793718

Phone

+98 53 3722 5027

Fax

+98 53 3722 3814

Email

kianmehr.m@gmu.ac.ir

Web page address

www.gmu.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Jalil Moshari

Position

Pediatrician / Assistant Professor

Other areas of specialty/work**Street address**

Gonabad University of Medical Sciences, Next to the Asian Road

City

Gonabad

Postal code

9691793718

Phone

+98 53 3722 5027

Fax

+98 53 3722 3814

Email

dr.moshari@gmu.ac.ir; dr.moshari@yahoo.com

Web page address

www.gmu.ac.ir

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

Gonabad University of Medical Sciences

Full name of responsible person

Mojtaba Kianmehr

Position

PhD in Biophysics / Assistant Professor

Other areas of specialty/work**Street address**

Gonabad University of Medical Sciences, Next to the Asian Road

City

Gonabad

Postal code

9691793718

Phone

+98 53 3722 5027

Fax

+98 53 3722 3814

Email

kianmehr.m@gmu.ac.ir

Web page address

www.gmu.ac.ir

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

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty