

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

the comparison between isotonic versus hypotonic rehydration therapy on the level of plasma sodium in children with gastroenteritis

Protocol summary

Summary

This is a Randomized double blind clinical trial Inclusion criteria were age 6 months to 14 years; without Diabetes Insipidus; hypothalamic diseases; pituitary diseases; renal disease; acute pulmonary disease; malnutrition ; cardiac diseases; hyponatremia at T0; hyperatremia at T0 and Exclusion criteria were hypernatremia(sodium above 150); Hyponatremia (Sodium Lower than 130); toxicity; low blood pressure. . Sample size was indicated 112 children aged 6 months to 14 years First outcome were indicated as hyponatremia in isonatremic and hyponatremic group T0 Isonatremic patients are included in the study AND based on block randomization were divided into two groups, A and B. For Group A First,20cc/kg isotonic saline (0.9%)were administered which could be repeated for 3 times, then 5% dextrose in isonatremic saline(0.9%) with 20meq/Lit were administered as loading and maintenance fluid and For Group B First,20cc/kg isotonic saline (0.9%)were administered which could be repeated for 3 times, then 5% dextrose in isonatremic saline(0.9%) with 20meq/Lit were administered as loading and maintenance fluid were administered . patients were assessed at 4 hours and 24 hours after reception.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211261545N2**
Registration date: **2012-12-23, 1391/10/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-23, 1391/10/03

Registrant information

Name

Hamidreza Badeli

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 9523

Email address

badeli@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

vice chancellor of research of Guilan University of Medical Sciences

Expected recruitment start date

2012-12-20, 1391/09/30

Expected recruitment end date

2013-04-20, 1392/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the comparison between isotonic versus hypotonic rehydration therapy on the level of plasma sodium in children with gastroenteritis

Public title

effect of normal saline on diarrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 6 months to 14 years; without Diabetes Insipidus; hypothalamic diseases; pituitary diseases; renal disease; acute pulmonary disease;

malnutrition ; cardiac diseases; hyponatremia at T0;
hyperatremia at T0 Exclusion criteria:
hypernatremia(sodium above 150); Hyponatremia (
Sodium Lower than 130); toxicity; low blood pressure.

Age

From **1 year** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-chancellor for research -Guilan University of
Medical Science

Street address

shahid siadati street

City

rasht

Postal code

Approval date

2012-05-23, 1391/03/03

Ethics committee reference number

1910095601

Health conditions studied

1

Description of health condition studied

gastroenteritis

ICD-10 code

K52.9

ICD-10 code description

Noninfective gastroenteritis and colitis, unspecified

Primary outcomes

1

Description

hyponatremia in isonatremic group

Timepoint

4 hours and 24 hours after reception

Method of measurement

the level of serum sodium concentration were evaluated
by ise method in electrolyte analyser

2

Description

hyponatremia in hyponatremic group

Timepoint

4 hours and 24 hours after reception

Method of measurement

the level of serum sodium concentration were evaluated
by ise method in electrolyte analyser

Secondary outcomes

empty

Intervention groups

1

Description

First, 20cc/kg isotonic saline (0.9%) were administered
which could be repeated for 3 times, then 5% dextrose in
hypotonic saline (0.45%) with 20meq/Lit were
administered as loading and maintenance fluid

Category

Treatment - Other

2

Description

First, 20cc/kg isotonic saline (0.9%) were administered
which could be repeated for 3 times, then 5% dextrose in
isonatremic saline (0.9%) with 20meq/Lit were
administered as loading and maintenance fluid

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

17 Shahrivar Hospital

Full name of responsible person

Dr Hamidreza Badeli

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research -Guilan University of Medical Science

Full name of responsible person

Dr Abdorrasoul Sobhani

Street address

Shahid Siadati Street

City

Rasht

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 -Guilan University of Medical Science

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**

Guilan University of Medical Sciences

Full name of responsible person

Hamidreza Badeli

Position

Nephrologist and associate professor of Guilan University of Medical Sciences

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

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Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Hamidreza Badeli

Position

Nephrologist and Associate Professor of Guilan University of Medical Sciences

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Person responsible for updating data

Contact**Name of organization / entity**

Guilan University of Medical Sciences

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Position

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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