Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Metoclopramide and serum therapy in control of vomiting in moderate dehydration due to Acute viral Gastroenteritis in children aged 1-7 years

Protocol summary

Summary

Introduction : Gastroenteritis is accompanied with high morbidity and mortality in pediatric patients. One of it's complications is dehydration which should be managed perfectly. We evaluated the use of metoclopramide in control of vomiting in children with acute gastroenteritis and moderate dehydration. Methods : in this double-blind randomized clinical trial study, we assigned 240 children aged 1-7 years old with vomiting due to Acute Viral Gastroenteritis to two groups of serum therapy(control) and metoclopramide(case).control group received 5% dextrose water solution along with electrolyte management while case group received 0.1 mg/kg Metoclopramide IV in addition. patients were followed for 4 days for number of vomiting episodes then data was analyzed using descriptive analysis , t-test and chi-square as appropriate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205159766N1**
Registration date: **2012-07-14, 1391/04/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-07-14, 1391/04/24

Registrant information

Name

Mohammadreza Firouzifar

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2010-03-21, 1389/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Metoclopramide and serum therapy in control of vomiting in moderate dehydration due to Acute viral Gastroenteritis in children aged 1-7 years

Public title

Metoclopramide and serum therapy in control of vomiting in moderate dehydration due to Acute viral Gastroenteritis in children aged 1-7 years

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-7 year old children with acute viral gastroenteritis; vomiting; moderate isonatremic dehydration; parenteral intolerance; no therapy prior to admission; no need for therapies other than those provided and written consent by parents. Exclusion criteria: mild or severe dehydration or hypo/hypernatremic moderate dehydration; laboratory results indicating active colitis e.g. blood , WBC or

parasite in stool exam; acute abdomen symptomes or any emergency situation; gastro aesophageal reflux and patient discontinuation and/or premature dismiss.

Age
From **1 year** old to **7 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **240**

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
Arak University of Medical Sciences Ethics Committee

Street address
Basij square, Arak University of Medical Sciences, Deputy of Research

City
Arak

Postal code

Approval date
2009-01-20, 1387/11/01

Ethics committee reference number
645 Behsan Software

Health conditions studied

1

Description of health condition studied
acute viral gastroenteritis

ICD-10 code
A08.3

ICD-10 code description
Other viral enteritis

Primary outcomes

1

Description
vomiting

Timepoint
everyday for 4 days

Method of measurement
by nurse

Secondary outcomes

1

Description
extrapyramidal symptomes

Timepoint
everyday for 4 days

Method of measurement
by nurse

Intervention groups

1

Description
addition of Metocloperamid 0.1 mg/kg to serum therapy in case group

Category
Treatment - Drugs

2

Description
standard serum therapy for isonatremic moderate dehydration as described by Nelson textbook of pediatrics in addition to electrolyte correction in control group as below : maintenance water is calculated as below for first 10 kg: 100 cc/kg for second 10 kg: 1000 cc + 50 cc/kg for over 20 kg: 1500 cc + 20 cc/kg 2400 cc maximum per day then we multiply that to the degree of dehydration(5-10%) and so the water deficit is calculated. first we treat the child with 20 cc/kg of NSS in 20 minutes. total water needed(maintenance+deficit)minus the NSS first treated is the amount to treat with dextrose water 5% plus 20 mEq/L KCl . if ongoing loss happens, for each ml of diarrhea 1 ml of DW5%+ 20 mEq/L NaHCO3 + 20 mEq/L KCl and for each ml of Vomiting 1 ml of NSS+ 10 mEq/L KCl is administered per 1-6 hours as needed.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Amirkabir Hospital

Full name of responsible person

Street address

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person

Dr. Hekmatpoo

Street address

Vice chancellor for research, Arak University of Medical Sciences , Arak

City

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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

Vice chancellor for research, Arak 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

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Full name of responsible person

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Position

Student of Medicine

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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