

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Effect of fast intravenous serum therapy on hospital admission rate of children with refractory vomiting and gastroenteritis referring to Tabriz Children's Hospital

#### Protocol summary

##### Summary

Our aim in this study is to evaluate the effect of fast intravenous serum therapy on hospital admission rate of children with gastroenteritis. In a randomized and unicentral clinical trial 70 children aged between 2 to 12 from both genders and with moderate gastroenteritis referring to emergency ward of Tabriz Children's Hospital would be involved. Key inclusion criteria would include children aged between 2 to 12 with diarrhea and vomiting which have not responded well to routine oral therapies; not to have electrolyte imbalance; not to have severe dehydration; to fulfill an informed consent and exclusion criteria would be to have mild or severe dehydration; to have electrolyte imbalance; in shock patients; patients with vomiting or diarrhea alone. Patients will randomly be divided into two control or case group each with 35 subjects. In control group patients will be admitted and visited by a specialist every day and in the case group patients will be treated with intravenous crystalloid solution 30 ml/kg infusion within 2 hours and then visited by a pediatrician to see if they need to be admitted to the internal ward. Primary outcome measures includes skin turgor, level of mucus dryness and desire to drink water; and secondary outcome measure would be occurrence of vomiting after intravenous therapy.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201110247892N1**

Registration date: **2012-05-03, 1391/02/14**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-05-03, 1391/02/14

##### Registrant information

###### Name

Anoosh Azarfar

###### Name of organization / entity

Mashhad University of Medical Sciences, Faculty of Nursing and Midwifery

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 1606 1227

###### Email address

azarfara@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2012-04-02, 1391/01/14

##### Expected recruitment end date

2013-01-03, 1391/10/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of fast intravenous serum therapy on hospital admission rate of children with refractory vomiting and gastroenteritis referring to Tabriz Children's Hospital

##### Public title

Does fast injection of therapeutic liquids lead to reduction in admission rate of children with

gastroenteritis?

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: (2 to 12 year old children with diarrhea and vomiting which have not responded well to routine oral therapies; not to have electrolyte imbalance; not to have severe dehydration; to fulfill an informed consent)

Exclusion criteria: (patients with mild or severe dehydration; to have electrolyte imbalance; in shock patients; patients with vomiting or diarrhea alone)

## Age

From **2 years** old to **12 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah square

##### City

Tabriz

##### Postal code

#### Approval date

2011-11-23, 1390/09/02

#### Ethics committee reference number

5/4/6665

## Health conditions studied

### 1

#### Description of health condition studied

Infective gastroenteritis

## ICD-10 code

A09.0

## ICD-10 code description

Other and unspecified gastroenteritis of infectious origin

## Primary outcomes

### 1

#### Description

Skin turgor

#### Timepoint

At the first time visited in the emergency ward, after receiving intravenous therapy.

#### Method of measurement

Physical examination by a pediatrician

### 2

#### Description

Mucosal dryness

#### Timepoint

At the first time visited in the emergency ward, after receiving intravenous therapy.

#### Method of measurement

Physical examination by a pediatrician

### 3

#### Description

Desire to drink water

#### Timepoint

At the first time visited in the emergency ward, after receiving intravenous therapy.

#### Method of measurement

Physical examination by a pediatrician

## Secondary outcomes

### 1

#### Description

Vomiting

#### Timepoint

While receiving intravenous serum or after receiving it

#### Method of measurement

Objective observation by a pediatrician

## Intervention groups

### 1

#### Description

Control group: Patients in this group will be admitted to the internal ward of the hospital and treated as appropriate

#### Category

Treatment - Drugs

## 2

### Description

Intervention group: patients in this group will receive an intravenous crystalloid 30 ml/kg within 2 hours and then visited by a pediatrician to see if they need a hospital admission to internal wards.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tabriz Children's Hospital

##### Full name of responsible person

Anoosh Azarfar, Assistant professor, Subspecialist in children's nephrology

##### Street address

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Alireza Ostad Rahimi

##### Street address

Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah square

##### City

Tabriz

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

### Full name of responsible person

Anoosh Azarfar

### Position

Assistant professor, subspecialist in children's nephrology

### Other areas of specialty/work

### Street address

Children's Hospital, Sheshgela st.

### City

Tabriz

### Postal code

### Phone

+98 41 1658 4153

### Fax

### Email

azarfar132@yahoo.com

### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Anoosh Azarfar

#### Position

Assistant professor, subspecialist in children's nephrology

#### Other areas of specialty/work

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## Person responsible for updating data

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#### Name of organization / entity

Tabriz University of Medical Sciences

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**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

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

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Data Dictionary**

**Statistical Analysis Plan**

*empty*