

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Randomized clinical trial : Evaluation of black tea tablets Effect in treatment of acute non-bacterial diarrhea in 2-12 years old patients referred to dastgheib hospital in Shiraz

#### Protocol summary

##### Summary

Objectives: Determine the effect of black tea in the treatment of acute diarrhea in children 2-12 years admitted to Dastgheib hospital in Shiraz and compared the percentage improvement with control group Design: The single blind randomized clinical trial without a placebo Setting and conduct: Patients were divided into two groups A and B. one group treated with black tea tablet and Standard treatment and the other group was given only standard treatment. After 24 hours the child was examined by a doctor. Participants including major eligibility criteria: Diarrhea that there is at least 3 times during 24 hours and also have changed in consistency. Excluding criteria: Bloody diarrhea (with OB + stool) or be mucoid, Access to them is not possible during the next 24 hours, Possible side effects or symptoms of disease are observed, Diagnosis of acute non-bacterial diarrhea and specific treatment is considered, Patients with known gastrointestinal problems such as celiac disease, lactase deficiency and malabsorption, Patients with underlying problems such as diabetes and immune deficiency, According to the doctor Consideration may need hospitalization or treatment, Significant fever and severe vomiting, cramps and dehydration, Patients with history of specific drug Intervention: Black tea tablets as a single-dose and standard treatment, Control group: Only standard treatment Main outcome measures : Change in bowel movements, change in stool volume and change in stool consistency This single blind randomized clinical trial study with out placebo is performed on 120 children (2-12 years old) with acute non-bacterial diarrhea that referred to Dastgheib hospital in Shiraz in 1390 who do'nt have bloody diarrhea and any underlying disease. they randomly divided to two group A and B. one group received black tea tablet and standard treatment and other group received only standard treatment. Children's healthy situation was

followed after 24 hours by doctors.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201108272434N6**

Registration date: **2012-03-31, 1391/01/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-03-31, 1391/01/12

##### Registrant information

##### Name

Mohammad Hadi Imanieh

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1647 4298

##### Email address

imaniehm@sums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Vice Chancellor for Research Shiraz University of Medical Sciences

##### Expected recruitment start date

2011-08-27, 1390/06/05

##### Expected recruitment end date

2012-02-24, 1390/12/05

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Randomized clinical trial : Evaluation of black tea tablets  
Effect in treatment of acute non-bacterial diarrhea in  
2-12 years old patients referred to dastgheib hospital in  
Shiraz

**Public title**

Evaluation efficacy of black tea tablets Effect in  
treatment of acute non-bacterial diarrhea

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion: There diarrhea (defined as the science) at least  
3 times in 24 hours; Exclusion:bloody and mocoid  
diarrhea(+OB) ; Lack of access to patients in the next 24  
hours ; Confirmed the diagnosis of acute non-bacterial  
diarrhea and need special treatment ; Gastrointestinal  
diseases such as celiac disease and lactose deficiency  
and ... ; Underlying problems such as diabetes, reduced  
immune system and ...

**Age**From **2 years** old to **12 years** old**Gender**

Both

**Phase**

2

**Groups that have been masked***No information***Sample size**Target sample size: **120****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 Shiraz University of Medical  
Sciences

**Street address**

Zand st

**City**

Shiraz

**Postal code****Approval date**

2011-07-11, 1390/04/20

**Ethics committee reference number**

5617-90

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

Acute Non-Bacterial Diarrhea

**ICD-10 code**

A08 , A09

**ICD-10 code description**

Viral and other specified intestinal infections , Other  
gastroenteritis and colitis of infectious and unspecified  
origin

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

Change in Bowel Frequency

**Timepoint**

Before intervention and 24 hours later

**Method of measurement**

Questionnaire

**2****Description**

change in Stool Consistency

**Timepoint**

Before intervention and 24 hours later

**Method of measurement**

Questionnaire

**3****Description**

change in stool Volume

**Timepoint**

Before intervention and 24 hours later

**Method of measurement**

Questionnaire

**Secondary outcomes****1****Description**

Require the use of ORS or IV injection

**Timepoint**

Every 6 hours

**Method of measurement**

Questions from Parents-Nurses

## Intervention groups

1

### Description

Intervention: Single dose of black tea tablet and standard treatment ; This drug is made from ordinary black tea in tablet form. In 2-6 years old children Was prescribed one tablet as a single dose and 6-12 years old children two tablet as a single dose.

### Category

Treatment - Drugs

2

### Description

Control: Standard treatment (ORS)

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Dastgheib Hospital in Shiraz

**Full name of responsible person**

Sareh Doost Fatemeh

**Street address**

**City**

Shiraz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice Chancellor for Research, Shiraz University of Medical Sciences

**Full name of responsible person**

Gholam Reza Hatam

**Street address**

Zand st

**City**

Shiraz

**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, Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Sare Doust Fateme

**Position**

Medical Student

**Other areas of specialty/work**

**Street address**

No 236, Doustan st, Mali Abad, Shiraz

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mohamad Hadi Imanieh

**Position**

Professor of pediatric gastroenterology

**Other areas of specialty/work**

**Street address**

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## Person responsible for updating data

### Contact

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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*