

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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 ...

AgeFrom **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

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Full name of responsible person

Mohamad Hadi Imanieh

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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