Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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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 ...
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
Questionaire

2

Description
change in Stool Consistency
Timepoint
Before intervention and 24 hours later
Method of measurement
Questionaire

3

Description
change in stool Volume
Timepoint
Before intervention and 24 hours later
Method of measurement
Questionaire

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
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Full name of responsible person
Sare Doust Fateme
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Person responsible for scientific inquiries

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Namazi Sq.

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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