Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of date kernel suspension on reduction of severity and duration of diarrhea in Patients with gastroenteritis

Protocol summary

Study aim
The effect of date kernel suspension on reduction of severity and duration of diarrhea in gastroenteritis patients

Design
This study is a double-blind randomized controlled clinical trial on patients with gastroenteritis referred to Abuzar hospitals in Ahvaz. . Eligible patients will then be randomly divided into two experimental and control groups. The age range of children between 2 years and 8 years was selected. At baseline, there was no difference between the two groups in terms of sex, age, diet, weight, duration of diarrhea, and degree of hydration. For the first group of palm kernel suspensions, 3% in the amount of 3 mg per kilogram of body weight is administered orally every 8 hours for 7 days. for the second group, placebo is prescribed every 8 hours.

Settings and conduct
abuzar children hospital . Intervention Patients were randomly divided into intervention and control groups (based on random number table). For the first group of palm kernel suspensions, 3% in the amount of 3 mg per kilogram of body weight is administered orally every 8 hours for 7 days. And for the second group, placebo is prescribed once every 8 hours.

Participants/Inclusion and exclusion criteria
Entry requirements: Patients with gastroenteritis, age between 24 and 96 months, no drug treatment before entering the study and completing the consent form Conditions of non-entry: 1-Severe dehydration 2-There are abnormal findings in stool tests such as wbc blood equal to or above 5 or parasite 3-There is a problem with surgery, such as acute abdominal surgery 4-Having another illness or taking another medicine while studying 5-Frequent vomiting and intolerance to the drug

Intervention groups
Patients were randomly divided into two intervention and control groups, randomly assigned to either the intervention or the placebo control group.

Main outcome variables
Severity and duration of diarrhea

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200202046341N1**
Registration date: **2020-06-22, 1399/04/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-22, 1399/04/02**
Update count: **0**

Registration date
2020-06-22, 1399/04/02

Registrant information

Name
Neda Mohtasham

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3551 2845

Email address
mohtasham-n@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2020-09-26, 1399/07/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of date kernel suspension on reduction of severity and duration of diarrhea in Patients with gastroenteritis

Public title
The effect of date kernel suspension on reduction of severity and duration of diarrhea in Patients with gastroenteritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All children aged 24 months to 96 months with acute gastroentrit No drug treatment before enrollment Completion of parental consent form Symptoms less than or equal to 24 hours

Exclusion criteria:
Severe dehydration Abnormal findings in stool exam such as wbc equal or above 5 in stool or parasite in stool There is a surgical problem such as acute abdominal surgery Having another illness or taking another drug while studying Failure to adhere to treatment protocol or abandon treatment before complete recovery Frequent vomiting and intolerance to medication Patient Withdrawal from Study Participation

Age
From **24 months** old to **96 months** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomly divided into two intervention and control groups according to the random number table. The intervention group received the suspension and the control group received placebo .

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, both participants and their parents, as well as researchers and evaluators, are unaware of the consequences of determining which group they are in.drug and placebo are given to patients based on a pre-determined random numbering.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
AhAhvaz Jundishapur University of Medical Science

Street address
Golestan

City
ahvaz

Province
Khouzestan

Postal code
61357-15794

Approval date
2020-03-14, 1398/12/24

Ethics committee reference number
IR.AJUMS.REC.1398.960

Health conditions studied

1

Description of health condition studied
Acute gastroenteritis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Assess the severity and duration of diarrhea

Timepoint
The efficacy of the drug in the first, second and seventh days

Method of measurement
Reduce the number of diarrhea at the end of the first, third and seventh days

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:For the first group, 3% palm kernel suspension is given at a dose of 3 mg per kg body weight orally every 8 hours for 7 days. for the control group, placebo is prescribed three times a day (once every 8 hours).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Abuzar Children's Hospital
Full name of responsible person
نادر شفیعی
Street address
زیتون
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3444 9003
Email
info@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
محمد بدوی
Street address
Golestan
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3373 8383
Fax
+98 61 3373 8383
Email
info@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Amanollah Zarei Ahmady
Position
دانشیار
Latest degree
Ph.D.
Other areas of specialty/work
Chemistry
Street address
Golestan
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3373 8382
Email
amanzarei@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Neda Mohtasham
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address
Zeytoon
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
0098613311
Fax
+98 61 3373 8383
Email
amanzarei@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Nader Shafiee

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

Street address
Zeytoon

City
Ahvaz

Province
Khouzestan

Postal code
61357-15794

Phone
+98 61 3373 8383

Email
amanzarei@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available