

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Double blind randomized clinical trial in treatment of gastroesophageal reflux disease in children with Myrtus Communis L. (Myrtle) fruit.

Protocol summary

Summary

This trial is a phase 3, single-center, randomized, double blinded, placebo controlled clinical trial to evaluate the effect of "myrtle fruit syrup" on Gastro-Esophageal Reflux Disease (GERD) in children. The sample size is 50 containing 25 in every group. 1 to 7 years old children attending gastroenterology clinic of Bahrami's children hospital who are diagnosed as GERD patients according to GSQ-YC (GERD Symptom Questionnaire-Young Child) and pediatric gastroenterologist are recruited in the study, are allocated to intervention group (omeprazole and "myrtle fruit syrup") or control group (omeprazole and placebo syrup). One week after starting the treatment, via telephone contact, parents are asked about the time when the maximum effect of treatment has been observed as well as satisfaction rate with syrup form and capsule form. Treatment period is 2 months. GERD Symptom Questionnaire for Young Child (GSQ-YC) will be filled out after 2 and 3 months from starting the treatment. Finally, comparison between questionnaires data will be done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061828521N1**

Registration date: **2016-09-04, 1395/06/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-04, 1395/06/14

Registrant information

Name

Maryam al-sadat Paknejad

Name of organization / entity

Tehran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 457 3486

Email address

m-paknejad@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-08-05, 1395/05/15

Expected recruitment end date

2017-11-06, 1396/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double blind randomized clinical trial in treatment of gastroesophageal reflux disease in children with Myrtus Communis L. (Myrtle) fruit.

Public title

The effect of myrtle fruit syrup on children reflux disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. 1 to 7 years old children attended to Bahrami's children hospital gastro-enterology clinic; 2. Diagnosis of GERD on the basis of GSQ-YC questionnaire and pediatric gastroenterologist; 3. Absence of serious gastrointestinal diseases such as esophagitis, achalasia, gastrointestinal ulcers, IBD (Inflammatory Bowel disease),....; 4. Absence of GERD complications such as:

esophagitis and ulcers; 5. Absence of every serious condition such as severe asthma; 6. Absence of gastrointestinal anomalies; 7. Absence of cognitive or mental disorders; 8. Absence of history of PPIs (Proton Pump Inhibitors) or H2 Blockers consumption in 1 week before; 9. Absence of severe constipation; Exclusion criteria: 1. Patient's lack of tendency to continue the trial; 2. Significant conditions which can be considered as drug side effects; 3. Exacerbation of GERD symptoms throughout the trial; 4. Allergy history to myrtle; 5. Significant history of allergy to herbal compounds or food allergy;

Age

From **1 year** old to **7 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double 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 Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Poursina St, 16 Azar St, Tehran, Iran.

City

Tehran

Postal code**Approval date**

2016-06-18, 1395/03/29

Ethics committee reference number

IR.TUMS.REC.1395.2699

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

gastroesophageal reflux disease

ICD-10 code

K21

ICD-10 code description

Gastro-oesophageal reflux disease

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

Vomiting / Regurgitation

Timepoint

0th, 2nd, 3rd month after treatment start

Method of measurement

GSQ-YC questionnaire

2**Description**

Choking when eating

Timepoint

0th, 2nd, 3rd month after treatment start

Method of measurement

GSQ-YC questionnaire

3**Description**

Abdominal pain

Timepoint

0th, 2nd, 3rd month after treatment start

Method of measurement

GSQ-YC questionnaire

4**Description**

Burping / belching

Timepoint

0th, 2nd, 3rd month after treatment start

Method of measurement

GSQ-YC questionnaire

5**Description**

Difficulty swallowing

Timepoint

0th, 2nd, 3rd month after treatment start

Method of measurement

GSQ-YC questionnaire

6**Description**

Refusal to eat

Timepoint

0th, 2nd, 3rd month after treatment start

Method of measurement

GSQ-YC questionnaire

Secondary outcomes

1

Description

side effect

Timepoint

any time throughout the survey

Method of measurement

babysitter report

2

Description

anti-acid use frequency

Timepoint

0th, 2nd, 3rd month after treatment start

Method of measurement

babysitter report

3

Description

drug's form satisfaction

Timepoint

7th day after treatment start

Method of measurement

babysitter report

4

Description

maximum efficacy

Timepoint

7th day after treatment start

Method of measurement

babysitter report

Intervention groups

1

Description

Intervention group is received omeprazole capsules and Myrtle fruit syrup. Omeprazole (Abidi®) will be prescribed 1 mg/kg/day in 2 divided Dose, 15 min before child feeding while Myrtle fruit syrup will be prescribed 0.21 mg/kg/day in 3 divided Dose, after child feeding. Treatment course will be 2 months.

Category

Treatment - Drugs

2

Description

Control group is received omeprazole capsules and placebo syrup. Omeprazole (Abidi®) will be prescribed 1 mg/kg/day in 2 divided Dose, 15 min before child feeding while placebo syrup will be prescribed 0.21 mg/kg/day in 3 divided Dose, after child feeding. Treatment course will

be 2 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahrami children's hospital

Full name of responsible person

Maryam al-sadat Paknejad

Street address

Shahid Kiaee Ave, Damavand Ave, Emam Hossein SQ, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Masud Yunesian

Street address

Central Building of Tehran University of Medical Sciences, Qods Ave, Keshavarz Blvd, Tehran, Iran.

City

Tehran

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, Tehran 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

faculty of traditional medicine of Tehran University of Medical Sciences

Full name of responsible person

Maryam al-sadat Paknejad

Position

PhD student of traditional medicine

Other areas of specialty/work**Street address**Khark Traditional Iranian Medicine Clinic, Khark st,
Enghelab st, Tehran, Iran**City**

Tehran

Postal code**Phone**

+98 26 3446 2488

Fax**Email**m-paknejad@razi.tums.ac.ir;
neurointmed@gmail.com; neurointmed@yahoo.com**Web page address****Web page address****Person responsible for updating data****Contact****Name of organization / entity**faculty of traditional medicine of Tehran University of
Medical Sciences**Full name of responsible person**

Maryam al-sadat Paknejad

Position

PhD Student of traditional medicine

Other areas of specialty/work**Street address**faculty of traditional medicine of Tehran University of
Medical Sciences, Khark st, Enghelab st, Tehran, Iran**City**

Tehran

Postal code**Phone**

+98 26 3446 2488

Fax**Email**m-paknejad@razi.tums.ac.ir;
neurointmed@gmail.com; neurointmed@yahoo.com**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**faculty of traditional medicine of Tehran University of
Medical Sciences**Full name of responsible person**

Dr. Mehrdad Karimi

Position

PhD of traditional medicine

Other areas of specialty/work**Street address**Ahmadih Iranian Traditional Medicine Clinic,
Sarparast st, Taleghani st, Tehran, Iran.**City**

Tehran

Postal code**Phone**

+98 21 6675 4166

Fax**Email**

mehrdadkarimi@yahoo.com

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*