Peppermint Oil for the treatment of Irritable Bowel Syndrome or Functional Abdominal Pain in Children: the MINT study

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Ethical review	Approved WMO
Status	Completed
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON52287

Source
ToetsingOnline

Brief title
MINT-study

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Functional abdominal pain, Irritable Bowel Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: Prins Bernhard Cultuurfonds

Intervention

Keyword: Childeren, Functional abdominal pain, Irritable bowel syndrome, Peppermint oil

Outcome measures

Primary outcome

The primary outcome measure is the percentage of children with >30% reduction in abdominal pain intensity after 8 weeks of treatment from baseline. Abdominal pain intensity is measured daily for 7 consecutive days using an abdominal pain app.

Secondary outcome

Secondary outcome measures are other recently internationally defined outcome measures for trials in children with chronic abdominal pain: degree of reduction in pain frequency and pain intensity, percentage of patients with an adequate improvement in complaints, school absenteeism hours, quality of life, feelings of anxiety & depression, defecation pattern, taste, ease of use and side effects of the treatment. In addition, genetic polymorphisms associated with susceptibility to placebos are investigated and related to both primary and secondary outcome measures.

Study description

Background summary

Irritable bowel syndrome (IBS) and functional abdominal pain (FAP) are common conditions in children. Every year, approximately 13,000 children in the Netherlands visit the pediatrician with this complaint. IBS and FAP are associated with a reduced quality of life and an increased risk of psychiatric

disorders. Therapeutic options include an explanation of the condition, painkillers, often in combination with dietary modifications, or psychological therapies such as hypnotherapy or cognitive behavioral therapy. Currently, there is no proven effective pharmacological treatment for children with IBS or FAP.

Peppermint oil is a very interesting therapeutic option to investigate further: it relaxes smooth muscle tissue in vitro and modulates visceral nociception. Two small studies of low quality in children suggest a positive effect on abdominal pain. A systematic review from 2020 in adults with IBS and a subsequently published Dutch study in adult IBS patients concluded that peppermint oil capsules lead to a reduction of complaints. Peppermint oil is therefore recommended in the recently published American treatment guideline for adults with IBS.

Pediatricians therefore regularly recommend peppermint oil capsules to children with FB or IBS, even though there is no convincing evidence of an effect in children. For a long time, peppermint oil capsules were not registered for children < 10 years and in that case, regular peppermints were often prescribed, with positive reported effects. As mentioned, the effectiveness of peppermint oil capsules in children has not been sufficiently studied and the effect of peppermints on abdominal pain has not been studied at all. In the first phase of formulating and planning this study, several (parents of) children with abdominal pain were consulted about the study design. They advised comparing peppermint oil capsules with both placebo capsules and peppermints because both research questions are important in their view.

Study objective

The aim of the Mint study is to investigate the effectiveness of peppermint oil capsules compared to placebo capsules in reducing abdominal pain intensity in these children. In addition, we investigate the effect of peppermint oil capsules compared to placebo capsules on other disease-related outcome measures such as anxiety & depression, quality of life, absenteeism from school, and healthcare costs. The second aim is to explore the effectiveness of regular mints in reducing abdominal pain intensity compared to peppermint oil capsules and placebo capsules and the effect of mints on secondary outcome parameters.

Study design

Multicenter, partially blinded, placebo-controlled study consisting of 3 groups (blinded peppermint oil capsules or placebo capsules and an open-label group with regular mints) with a treatment duration of 8 weeks and a follow-up period of 4 weeks.

Intervention

Peppermint oil capsules 182 mg 2 d.d.1 capsules (8-11 years) or 3 d.d. 1 capsule (12-18 years) versus placebo capsules versus regular mints 2-3 times 1 day for 8 weeks

Study burden and risks

The subjects have to visit the pediatric department twice in 12 weeks. Moreover, the subjects and their parents, separately, have to fill out questionnaires and a pain diary on an app four times: (I) at the start of the baseline period, (II) in the fourth week of the study (III) in the eight week of the study (end of treatment), and (IV) four weeks after the end of treatment. Patients will be randomly allocated to peppermint oil capsules, placebo capsules, or peppermints. Also, a saliva swab will be taken for DNA studies. Side-effects of peppermint oil capsules are generally mild and transient of nature.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Children aged between 8 and 18 years
Diagnosos of IBS or FAP-NOS according to the Rome IV-criteria.
Patients are required to have an average daily pain rate of >=2 on the Wong-Baker Faces Pain Scale

Exclusion criteria

Current treatment by another health care professional for abdominal symptoms
Previous use of peppermint oil for abdominal complaints
Known hypersensitivity to mints or peppermint oil
Gastrointestinal blood loss
Recurrent or unexplained fevers
Decreased growth velocity
History of previous abdominal surgeries in the past 3 months
Significant chronic health condition requiring specialty care (e.g., lithiasis, ureteropelvic junction obstruction, sickle cell, cerebral palsy, hepatic, hematopoietic, renal, endocrine, or metabolic diseases) that could potentially impact the child*s ability to participate or confound the results of the study
Known concomitant organic gastrointestinal disease
Current use of drugs which influence gastrointestinal motility, such as erythromycin, azithromycin, butyl scopolamine, domperidone, mebeverine and Iberogast. If laxatives are being used (in patients with IBS-C) they can continue using them during the study.
Current use of proton-pump inhibitors
Insufficient knowledge of the Dutch language
Pregnancy or current lactation. Women with childbearing potential must have a negative urine pregnancy test within 7 days prior to first dose of study treatment

Study design

Design

Study phase:	3
Study type:	Interventional

Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	06-05-2022
Enrollment:	240
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Tempocol
Generic name:	Peppermint Oil
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Wilhelmina Peppermints
Generic name:	Peppermint

Ethics review

Approved WMO

Date:	21-09-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	10-11-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	07-03-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-03-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2021-003690-65-NL
CCMO	NL78304.100.21