THE EFFECT OF PROBIOTICS ON THE FREQUENCY AND INTENSITY OF MIGRAINE ATTACKS AND INTESTINAL PERMEABILITY - A PLACEBO-CONTROLLED TRIAL

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To test whether probiotics, as adjuvant therapy, can reduce incidence and severity of migraine attacks by reducing intestinal permeability.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON38953

Source
ToetsingOnline

Brief title
Probiotics and Migraine: the Promi2 study

Condition

- Gastrointestinal signs and symptoms
- Headaches

Synonym
migraine, unilateral headache

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,IPC Project

Intervention

Keyword: intestinal permeability, migraine, probiotics

Outcome measures

Primary outcome

Incidence of migraine (measured by diaries, number of days with migraine in 4 weeks)

Secondary outcome

Severity of migraine attacks, measured by diaries and validated headache questionnaires will be measured at baseline and after 4, 8, and 12 weeks of probiotic/placebo administration. Further, intestinal permeability will be measured by the lactulose/mannitol absorption test in urine (screening, baseline and 12 weeks) and by fecal zonulin (baseline, 4, 8, and 12 weeks). Inflammation will be assessed from blood C-reactive protein and cytokine concentrations (baseline, 4, 8, and 12 weeks). Fecal samples will also be used for microbial analysis.

Study description

Background summary

The prevalence of migraine is higher in patients with various intestinal diseases. An explanation could be that migraine is caused by a *leaky gut*: an increased intestinal permeability that allows food particles to pass the gastrointestinal wall. Probiotics may be able to improve intestinal barrier

function.

Study objective

To test whether probiotics, as adjuvant therapy, can reduce incidence and severity of migraine attacks by reducing intestinal permeability.

Study design

12-week placebo-controlled randomized double-blind intervention with selected probiotics.

Intervention

Subjects will receive either one daily dose of 2 g of Ecologic® Barrier or 2 grams of the placebo, containing only the carrier material (both provided by Winclove Probiotics).

Study burden and risks

The lactic acid bacteria in the mixture carry the European Union Qualified Presumption of Safety (QPS). No side effects are expected. The probiotic mixture is available on the Dutch market for relief of gastrointestinal complaints. The product has been used before in the ProMi study with migraine patients, with no adverse effects. Invasive measurements are restricted to blood sampling; collection of urine and feces may be considered unpleasant. If patients benefit from the probiotic intervention, this will help their management of migraine.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Subjects confirm to have migraine characterized by :
o Recurrent attacks of moderate to severe headaches, often one-sided and pounding, often with nausea and/or vomiting, aggravated by physical activity
o Sensitivity for light or sounds is possible but not exclusive.
o Attacks last for 4 to 72 hours.
- Self-reported frequency of migraine attacks (or days) at least 4 per month
- Fairly predictable/stable pattern of migraine attacks (frequency, duration, intensity)
- Age >= 18 years
- General good health

Exclusion criteria

- Migraine patients who suffer from chronic daily migraine/headaches
- Migraine patients who suffer from medication-dependent headaches
- Subjects who suffer from cluster headache or tension-type headaches
- Subjects who used antibiotics up to two months before the start of the study
- Pregnancy or lactation (because of their possible effect on migraine incidence
- Patients who are unwilling to stop current use of probiotics
- Patients who have a chronic use of NSAIDs
- patients with inflammatory bowel diseases

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-02-2014
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	20-12-2013
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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
CCMO	NL46401.081.13