

The effect of oral ingestion of probiotics on the frequency and intensity of migraine attacks

Published: 12-01-2012

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To investigate whether probiotics can reduce incidence and severity of migraine attacks.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Headaches
Study type	Interventional

Summary

ID

NL-OMON35284

Source

ToetsingOnline

Brief title

Probiotics and migraine

Condition

- Headaches

Synonym

cephalagia, Headache

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: Ministerie van OC&W, Winclove Bio Industries BV

Intervention

Keyword: Intestinal Mucosa, Migraine, Probiotics

Outcome measures

Primary outcome

Incidence and severity of migraine attacks, measured by headache diaries

Secondary outcome

The disability due to migraine attacks is measured by validated headache questionnaires (MIDAS and HDI questionnaire).

Study description

Background summary

Some theories suggest that migraine is caused by a *leaky gut*: an increased intestinal permeability that allows undigested food particles to pass the gastrointestinal wall. These components may cause migraine attacks. Probiotics may be able to improve intestinal barrier function, and in this way, the frequency and intensity of migraine attacks may reduce.

Study objective

To investigate whether probiotics can reduce incidence and severity of migraine attacks.

Study design

Open label, linear study (before-after design).

Intervention

One dose per day of 2 g of Ecologic® Barrier (Winclove).

Study burden and risks

The probiotic mixture is available on the Dutch market for relief of gastrointestinal complaints. The lactic acid bacteria in the mixture carry the

European Union Qualified Presumption of Safety (QPS). No side effects are expected. No invasive measurements are performed. If patients benefit from the treatment, this will increase their treatment options for 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

- Frequency of at least 4 migraine attacks (or days) per month
- Pattern of migraine attacks predictable/stable (frequency, duration, intensity)
- Preferably: migraine patients with self-reported gastrointestinal complaints (before, during or after their migraine attacks), such as diarrhoea, bloating, or constipation.

Exclusion criteria

- chronic daily migraine
- medication-dependent headaches
- cluster headache or tension-type headaches
- antibiotics use up to two months before the start of the treatment period
- probiotics use up to two weeks before the start of the treatment period
- Female migraine patients who are pregnant or lactating (the migraine pattern is influenced).

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-01-2012

Enrollment: 30

Type: Anticipated

Ethics review

Approved WMO

Date: 12-01-2012

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	NL38763.081.11