Comparison of taste and texture of Metamucil®, Volcolon® and psyllium orange generic

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Comparison of 1. taste and 2. texture/palatability of Metamuci orangel®, Volcolon® and generic orange psyllium.

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

Summary

ID

NL-OMON43055

Source
ToetsingOnline

Brief title
Comparison of taste and palatability in fiber supplements

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Constipation, infrequent evacuation of the bowels

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: TEVA Pharma Nederland

Intervention

Keyword: constipation., fibers, Taste, texture

Outcome measures

Primary outcome

The results concerning taste and texture will be noted on a form with a Likert

5- point scale (two different questions):

1 = very poor taste / unpleasant

2 = poor taste / unpleasant

3 = neutral

4 = tasty / pleasant

5 = very tasty/ very pleasant

All results will be analyzed and testes with the Friedman test. Addittionally a

Wilcoxon test can be performed when necessary. Considering a standard deviation

per formula of 1 with * 0.05 and * 80% at a sample size of 100 persons a

difference 0.4 can be demonstrated.

Secondary outcome

Not applicable.

Study description

Background summary

A pleasant taste of a prescription improves patient compliance and adherence.
According to the literature, only 50% of patients who suffer from chronic

diseases adhere to treatment recommendations (1). This results in suboptimal outcomes (2). There are numerous factors that affect adherence, including characteristics of the illness, interaction between physician and patient, the complexity and duration of treatment, side effects of treatment and costs of treatment (3). Furthermore, medication palatability is also crucial for adherence. Several studies have addressed the palatability of medication for different disorders, like hypertension, HIV and Alzheimer*s disease (4-6). Therefore, pharmaceutical companies pay attention to manufacture more formulations and add pleasant flavours which may improve the palatability.
Fiber supplements are increasingly used for treatment of chronic constipation both in adults and children. In the Netherlands several formulas are available such as Metamucil orange®, Volcolon® en generic psylium orange. These are effective and save formulas. Little literature is available concerning taste and laxatives or fibers, although many patients complain about taste and texture of the preparations. Studies with polyethylene glycol preparations performed by our research group demonstrated some differences in palatability between these preparations (7-9).
There are hardly any studies about fibers and taste. The taste is mentioned to be acceptable; one study compares dried prunes with psylium and concludes there is no difference in taste experience (10).
In order to improve patient compliance, it is of clinical importance to know which preparations are the most acceptable to the patient, and use that as first choice. We hypothese that the taste and palatibility of Metamucil orange® is preferable.

References:
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Study objective

Comparison of 1. taste and 2. texture/palatability of Metamuci orangel®, Volcolon® and generic orange psyllium.

Study design

It is a double blind, randomized, crossover study.

Intervention

All healthy volunteers will try the 3 different formulas. After swallowing the first formula, the mouth will be rinsed with water. Then the second formula will be tried, after rinsing the mouth again the third formula will be tried. Every time after tasting a formula, the questionnaire is filled in, before starting with the next formula. The maximum intake is 3 x 25 ml (75 ml), this is 37,5% of one dosage advised quantity of fibre. The sequence in which the formulas are tasted is randomized.

Preparations and dosage

Each sachet needs to be solved in a glass of water. This matches (approximately) 200 ml. During the study the volunteers will taste 3 x 25 ml of water. This matches 37,5% of one dosage. The average intake of psyllium fibers is 1-3 sachets a day.
Dosage if the different products:
- Volcolon sugar free (Dutch name: Volcolcolon suikervrij): 1 sachet contains 4 g powder
o 980mg/g psyllium fibers x 4 g per sachet = 3.92 g psyllium fibers/sachet
o So 25 ml contains 0.490 g psyllium fibers
- Metamucil Orange: 1 sachet contains 3.4 g psyllium fibers
o So 25 ml contains 0.425 g psyllium fibers
- Psyllium Orange: 1 sachet contains 3.25 g psyllium fibers
o So 25 ml contains 0.406 g psyllium fibers

These three products are the most used products for each brand (Metamucil orange, Volcolon and generic orange). This leads to the greatest coverage of the three brands in the Netherlands. The volunteers will swallow 25 ml of each product, three in total. This leads to an intake of 1.32 g (0.490 g + 0.425 g +

0.406= 1.32 g) psyllium fibers. According to the Dutch Board of Health (in Dutch: Gezondheidsraad) the average intake of fibers should be between 30 and 40 g a day. So, the volunteers will swallow approximately 4% (3.3 * 4.4%) of the advised intake of fibers. Therefore, we do not expect any problems when the volunteers swallow these products.

Study burden and risks

The maximum intake is 3 x 25 ml (75 ml), this is 37,5% of one dosage advised quantity of fibre. Therefore, we do not expect any problems when the volunteers swallow these products.

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

Healthy volunteers, age 18-70 years, in good health, able to understand the instruction and give informed consent.

Exclusion criteria

Gastro-intestinal problems, swallowing disorders, rheumatic related diseases, known hypersentivity to the study medication.

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	07-10-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-11-2016
Application type:	Amendment

Review commission: METC Amsterdam UMC

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
ClinicalTrials.gov	NCT02867917
CCMO	NL57970.029.16