A 12-week, randomised, double-blind, placebo-controlled trial to evaluate the efficacy, quality of life, safety and tolerability of prucalopride in male subjects with chronic constipation.

Published: 13-07-2010
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Primary: To evaluate the efficacy of prucalopride versus placebo over 12 weeks of treatment in male subjects with chronic constipation.Secondary: To evaluate the safety, tolerability, effect on quality of life and effect on symptoms of prucalopride...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Interventional

Summary

ID

NL-OMON39176

Source
ToetsingOnline

Brief title
M0001-C302

Condition

- Gastrointestinal stenosis and obstruction

Synonym
constipation, obstipation

Research involving
Human

Sponsors and support

Primary sponsor: Shire-Movetis NV
Source(s) of monetary or material Support: Shire-Movetis NV

Intervention

Keyword: constipation, male subjects, prucalopride

Outcome measures

Primary outcome

Proportion (%) of subjects with an average of >= 3 SCBMs/week (i.e. a responder)

over the 12-week double-blind treatment period.

Secondary outcome

- Proportion (%) of subjects with an average increase of >= 1 SCBMs/week

compared to the run-in period, over the entire treatment period.

- The average number of (SC)BM/week and change from baseline

- Number of (SC)BMs per week: descriptive statistics and distribution in

categories as 0, (0;1), [1;2), [2;3), [3:*)

- Consistency per (SC)BM: descriptive statistics of 7-point score and % (SC)BM

with normal consistency (Type 3 or 4 on the Bristol stool scale).

- For more secondary endpoints, please refer to the study protocol.

Study description

Background summary

Prucalopride (Resolor®) is a new drug to stimulate intestinal motility. It recently received a marketing authorization for the symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief. Prucalopride belongs to a new chemical class of

dihydrobenzofuran-carboxamide derivatives with strong enterokinetic activity.

Study objective

Primary: To evaluate the efficacy of prucalopride versus placebo over 12 weeks of treatment in male subjects with chronic constipation.

Secondary: To evaluate the safety, tolerability, effect on quality of life and effect on symptoms of prucalopride versus placebo over 12 weeks of treatment in male subjects with chronic constipation.

Study design

This is a multi-centre, randomised, parallel-group, double-blind, placebo-controlled phase II trial in male subjects with chronic constipation.

Subjects will be screened and enter a 2- or 3-week run-in period during which the presence of constipation will be confirmed. After the run-in period subjects will be randomly assigned to placebo or prucalopride in an equal ratio (1:1) if the subject fulfils the constipation criteria for inclusion. The subjects will take 2 or 1 mg (depending on the age and response of the subject) prucalopride or placebo once daily before breakfast during the entire 12-week treatment period.

Intervention

Subjects will take the study medication (placebo or prucalopride) daily during the study.

Study burden and risks

Data from phase II and phase III trials show that prucalopride is safe and well tolerated in all patient groups studied to date, including the elderly and children. The majority of side effects were mild to moderate in intensity and transient. Laboratory and cardiovascular safety data showed no clinically relevant changes during the course of treatment. The most frequently reported adverse events (AEs) were headache, abdominal pain, nausea and diarrhea. Most of these AEs occurred during the first week of treatment and were transient. The subjects will visit the trial center at screening, baseline and after 2, 4, 8 and 12 weeks of treatment. During these visits, the following procedures will take place: physical examination, blood and urine sampling, ECG, questionnaires. Subjects are also asked to keep an electronic diary. If the patients have no stool in 3 consecutive days, they are allowed to take rescue medication.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- subject is male out-patient >= 18 years of age.
- subject has a history of constipation, i.e. reports an average of <= 2 spontaneous bowel movements (SBM)/week, that result in a feeling of complete evacuation (SCBM) and one or more of the following for at least 6 months before the selection visit: - very hard (little balls) and/or hard stools for at least a quarter of the stools; - sensation of incomplete evacuation following for at least a quarter of the stoold; - straining at defecation for at least a quarter of the time. These criteria are only applicable for SBMs, i.e. BNs not preceded within a period of 24 hours by the intake of a laxative agent or by the use of an enema. Subjects who never have SBMs are considered to be constipated and are eligible for the trial.
- Subject agrees to stop his current laxative treatment and is willing to use rescue medication according to the rescue rule (bisacodyl (Dulcolax) / enemas).

Exclusion criteria

- Subjects in whom constipation is thought to be drug-induced.
- Subjects using any disallowed medication.
- Subjects suffering from secondary causes of chronic constipation.

Study design

Design

Study phase:	3
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):	03-02-2011
Enrollment:	18
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dulcolax
Generic name:	bisacodyl
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Resolor
Generic name:	Prucalopride
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	13-07-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-09-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-11-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-11-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-11-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-11-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-01-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	

Date:	24-01-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-03-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	11-05-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-05-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-06-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-06-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-06-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-07-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

	Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-09-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-09-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-12-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	15-12-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	05-03-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-03-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-05-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-06-2012

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-01-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-01-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-02-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-02-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	31-07-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-10-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-10-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2009-015719-42-NL
ClinicalTrials.gov	NCT01147926
CCMO	NL32873.068.10