A Multicenter Randomized Parallel Group Phase III Study Comparing the Bowel Cleansing Efficacy, Safety and Tolerability of NER1006 (a Low Volume Bowel Cleansing Solution) versus a Sodium Picosulfate and Magnesium Salt (SP+MS) Solution Using a Day Before-Only Dosing Regimen in Adults

Published: 07-10-2014
Last updated: 22-04-2024

Primary Objectives: To evaluate the overall bowel cleansing efficacy and the *Excellent plus Good* cleansing rate in the colon ascendens of a 1-day day before-only split-dosing regimen with NER1006 compared to a 1-day day before-only split-dosing...

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

Summary

ID

NL-OMON41935

Source
ToetsingOnline

Brief title
NER1006-03/2014

Condition

- Gastrointestinal signs and symptoms

Synonym
Bowel cleansing prior to colonoscopy

Research involving
Human

Sponsors and support

Primary sponsor: Norgine
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: Bowel cleansing, NER1006, SP+MS

Outcome measures

Primary outcome

1. The overall bowel cleansing success rate of NER1006 is non-inferior to that of SP+MS using the HCS, wherein success corresponds to Grades A and B, and failure corresponds to Grades C and D.

2. The *Excellent plus Good* cleansing rate in the colon ascendens of NER1006 is non-inferior to that of SP+MS using the segmental cleansing scoring system of the HCS, wherein the ordinal score of 4 corresponds to Excellent cleansing and score of 3 corresponds to Good cleansing.

Secondary outcome

Key secondary endpoints:

• ADR as defined by the proportion of patients with at least one adenoma in the colon ascendens as confirmed by a pathologist.

• ADR as defined by the proportion of patients with at least one adenoma in the overall colon as confirmed by a pathologist.

• PDR as defined by the proportion of patients with at least one polyp in the

colon ascendens, as confirmed by the colonoscopist.

• PDR as defined by the proportion of patients with at least one polyp in the

overall colon as confirmed by the colonoscopist.

Study description

Background summary

Bowel cleansing before a surgery/procedure is annoying for patients. Mainly due to the big amount of fluid that should be taken. This IP requires intake of less fluid. Moreover, the IP would cause better visibility of polyps/lesions etc.

Study objective

Primary Objectives:
To evaluate the overall bowel cleansing efficacy and the *Excellent plus Good* cleansing rate in the colon ascendens of a 1-day day before-only split-dosing regimen with NER1006 compared to a 1-day day before-only split-dosing regimen with SP+MS, graded according to the Harefield Cleansing Scale© (HCS©) in patients undergoing screening, surveillance or diagnostic colonoscopy.

Study design

This is a multicenter, randomized, colonoscopist-blinded study in patients undergoing a screening, surveillance or diagnostic colonoscopy.

Intervention

NER1006 Administration
NER1006: 1-Day Day Before-Only Split-Dosing Regimen (to commence in the evening of the day before colonoscopy).
SP+MS Administration
SP+MS: 1-Day Day Before-Only Split-Dosing Regimen (to commence in the morning of the day before colonoscopy).

Study burden and risks

Patienten must keep a diary and complete questionnaires.

Adverse events:

NER1006: Diarrhoea and allergic reactions including rash, urticaria, itching, angioedema and anaphylaxis are a possibility.

CitraFleet: abdominal pain and nausea, and from the consequences of diarrhoea and dehydration (sleep disturbance, dry mouth, thirst, headache and fatigue).

Contacts

Public
Norgine

Norgine House, Widewlace, Moorhall Road UB9 6NS
Harefield, Uxbridge UB9 6NS
GB
Scientific
Norgine

Norgine House, Widewlace, Moorhall Road UB9 6NS
Harefield, Uxbridge UB9 6NS
GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients will be entered into this study only if they satisfy the following criteria:
1.Patients must provide written informed consent.
2.Male and female outpatients and inpatients aged: >=18 to <=85 years undergoing a screening, surveillance or diagnostic colonoscopy.

3.Females of child bearing potential must have a negative pregnancy test at Screening and at Visit 2 and must be practising one of the following methods of birth control and agree to continue with the regimen throughout the study period (unless post-menopausal or surgically sterile):
•Oral, implantable, or injectable contraceptives (for a minimum of three months before study entry) in combination with a condom;
•Intrauterine device in combination with a condom;
•Double barrier method (condoms, sponge diaphragm, or vaginal ring with spermicidal jellies or cream);
If any female patient has a positive pregnancy test at Visit 2, they will be excluded from further participation in the study for the efficacy evaluation, i.e. they will not undergo the colonoscopy procedure. The Investigator will be required to arrange a colonoscopy procedure outside of the study.
4.Willing, able and competent to complete the entire study and to comply with instructions.

Exclusion criteria

Patients will be excluded from this study if they meet any of the following criteria:
1.Patients with past history within last 12 months or current episode of severe constipation (requiring repeated use of laxatives/enema or physical intervention before resolution), known or suspected ileus, gastrointestinal obstruction, gastric retention, bowel perforation, toxic colitis or megacolon.
2.Patients with ongoing severe acute Inflammatory Bowel Disease (IBD).
3.Patients who have had previous significant gastrointestinal surgeries, including colonic resection, sub-total colectomy, abdomino-perineal resection, de-functioning colostomy, Hartmann's procedure and defunctioning ileostomy or other similar surgeries involving structure and function of the small or large colon.
4.Regular use of laxatives or colon motility altering drugs in the last month (i.e. more than 2-3 times per week) in the last 28 days prior to the Screening Visit and/or laxative use within 72 hours prior to administration of the preparation.
5.Patients with active intestinal bleeding episodes or with a clinically significant low hemoglobin level <9 g/dL for women and <11 g/dL for men at screening.
6.Known glucose-6-phosphate dehydrogenase (G6PD) deficiency.
7.Known phenylketonuria.
8.Known hypersensitivity to polyethylene glycols, ascorbic acid, sulfates (not including sulfa-based products), sodium picosulfate and magnesium salt compounds, or any other

component of the investigational product or comparator.
9.Past history within the last 12 months or evidence of any on-going clinically relevant electrocardiogram (ECG) abnormalities (e.g. arrhythmias).
10.History of uncontrolled hypertension with systolic blood pressure >170 mmHg and diastolic blood pressure >100 mmHg.
11.Patients with cardiac insufficiency NYHA grades III or IV.
12.Patients with moderate to severe renal insufficiency (i.e. with GFR,<60 mL/min/1.73m2).
13.Patient with serum albumin <3.4 g/dL.
14.Patients with known liver disease of grades B and C according to the Child Pugh classification.
15.Patients suffering from dehydration at screening as evaluated by the Investigator from physical examination and laboratory investigations.
16.Patients with clinically significant electrolyte abnormalities, whether pre-existing or noted at screening, such as hypernatremia, hyponatremia, hyperphosphatemia, hypermagnesemia, hypokalemia, hypocalcaemia, dehydration, or those secondary to the use of diuretics or angiotensin converting enzyme (ACE) inhibitors.
17.Patients with any other clinically significant hematological parameters including coagulation profile at screening.
18.Patients with impaired consciousness that might predispose them to pulmonary aspiration.
19.Patients undergoing colonoscopy for foreign body removal and/or decompression.
20.Patients who are pregnant or lactating, or intending to become pregnant during the study.
21.Clinically relevant findings on physical examination based on the Investigator's judgment.
22.History of drug or alcohol abuse within the 12 months prior to dosing.
23.Concurrent participation in an investigational drug or device study or participation within three months of study entry.
24.Patients who, in the opinion of the Investigator, should not be included in the study for any reason, including inability to follow study procedures, e.g. cognitively impaired, debilitated or fragile patients.
25.Patients who are ordered to live in an institution on court or authority order.
26.Patients with a history of rhabdomyolysis.

Study design

Design

Study phase: 3

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-03-2015
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	CITRAFLEET
Generic name:	CITRAFLEET
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	NER1006
Generic name:	NER1006

Ethics review

Approved WMO

Date:	07-10-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	29-12-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	18-02-2015

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-03-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-08-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-08-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2014-002186-30-NL
CCMO	NL50449.091.14