



Clinical trial results:

Efficacy of a novel 1l PEG plus ascorbate (Plenvu) bowel preparation vs. 2l PEG plus ascorbate (Moviprep), a randomized controlled multicenter trial (PLEMO)

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2018-003304-39 |
| Trial protocol | DK |
| Global end of trial date | 10 April 2022 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 17 December 2023 |
| First version publication date | 17 December 2023 |

Trial information

Trial identification

| | |
|-----------------------|-----|
| Sponsor protocol code | 007 |
|-----------------------|-----|

Additional study identifiers

| | |
|------------------------------------|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | - |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Digestive disease center, Bispebjerg Hospital |
| Sponsor organisation address | Bispebjerg Bakke 23, Copenhagen NV, Denmark, 2400 |
| Public contact | Morten Rasmussen, Morten Rasmussen, morten.rasmussen@regionh.dk |
| Scientific contact | Morten Rasmussen, Morten Rasmussen, morten.rasmussen@regionh.dk |

Notes:

Paediatric regulatory details

| | |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 22 November 2023 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 10 April 2022 |
| Global end of trial reached? | Yes |
| Global end of trial date | 10 April 2022 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the bowel cleansing efficacy of either 1L PEG with ascorbate or 2L PEG with ascorbate in a randomized controlled trial including persons participating in the Danish national bowel screening program.

Protection of trial subjects:

The Danish Data Protection Agency

Background therapy: -

Evidence for comparator: -

| | |
|---|-----------------|
| Actual start date of recruitment | 17 October 2019 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|---------------|
| Country: Number of subjects enrolled | Denmark: 1275 |
| Worldwide total number of subjects | 1275 |
| EEA total number of subjects | 1275 |

Notes:

Subjects enrolled per age group

| | |
|---|-----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 681 |
| From 65 to 84 years | 594 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Participants in the Danish national bowel cancer screening scheduled for colonoscopy at Bispebjerg Hospital will be contacted by a study nurse for the purpose of study recruitment. All participants will be offered the possibility for a consultation with an investigator prior to consenting for participation.

Pre-assignment

Screening details:

Participants scheduled for a screening colonoscopy at Bispebjerg Hospital

Age 50-74 years

Possibility for participants to receive electronic documents

Telephone number to participants available

Period 1

| | |
|------------------------------|--|
| Period 1 title | Intervention (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Single blind ^[1] |
| Roles blinded | Investigator, Monitor, Data analyst ^[2] |

Arms

| | |
|------------------------------|-----------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Intervention (1L PEG + Asc) |

Arm description:

Participants randomized to receive intervention (1L polyethylene glycol + ascorbate)

| | |
|--|----------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Plenvu |
| Investigational medicinal product code | A06A D65 |
| Other name | |
| Pharmaceutical forms | Powder for oral suspension |
| Routes of administration | Oral use |

Dosage and administration details:

Powder for Oral Solution consisting of one sachet of Dose 1 and two sachets (A & B) for Dose 2.

- Dose 1 taken in the evening before the colonoscopy (approximately 18.00)

- Dose 2 taken in the early morning of the day of the colonoscopy.

Dose 1: The contents of the sachet for Dose 1 should be dissolved in 500 ml of water. The solution should be taken over a period of 30 minutes, followed by at least 500 ml of clear fluid over the next 30 minutes.

Dose 2: The contents of the two sachets (sachets A and B) for Dose 2 should be dissolved with 500 ml of water. The solution should be taken over a period of 30 minutes, followed by at least 500 ml of clear fluid over the next 30 minutes.

In addition to the fluids taken as part of the course of treatment, any amount of supplementary clear fluid (e.g. water, clear soup, fruit juice without pulp, soft drinks, tea and/or coffee without milk) may be taken.

| | |
|------------------|------------------------|
| Arm title | Control (2L PEG + Asc) |
|------------------|------------------------|

Arm description:

Participants randomized to receive control (2L polyethylene glycol + ascorbate)

| | |
|----------|-------------------|
| Arm type | Active comparator |
|----------|-------------------|

| | |
|--|--------------------------|
| Investigational medicinal product name | Moviprep |
| Investigational medicinal product code | A06A D |
| Other name | |
| Pharmaceutical forms | Powder for oral solution |
| Routes of administration | Oral use |

Dosage and administration details:

Dose 1 + 2: Powder for Oral Solution consisting of one sachet of Dose A and one sachet of Dose B.

- Dose 1 taken in the evening before the colonoscopy (approximately 18.00)
- Dose 2 taken in the early morning of the day of the colonoscopy.

Dose 1 + 2: The contents of sachet A and B should be dissolved in 1 litre of water. The solution should be taken over a period of one to two hours, followed by at least 500 ml of clear fluid

In addition to the fluids taken as part of the course of treatment, any amount of supplementary clear fluid (e.g. water, clear soup, fruit juice without pulp, soft drinks, tea and/or coffee without milk) may be taken.

Notes:

[1] - The number of roles blinded appears inconsistent with a single blinded trial. It is expected that there will be one role blinded in a single blind trial.

Justification: This is single-blinded (to investigator). Double blinding was not possible

[2] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: This is single-blinded (to investigator). Double blinding was not possible

| Number of subjects in period 1 | Intervention (1L PEG + Asc) | Control (2L PEG + Asc) |
|---|------------------------------------|-------------------------------|
| Started | 629 | 646 |
| Completed | 615 | 628 |
| Not completed | 14 | 18 |
| Requested colonoscopy at other hospital | - | 4 |
| Consent withdrawn by subject | - | 1 |
| Physician decision | - | 1 |
| Non appearance | 3 | 1 |
| Unknown reasons | - | 1 |
| Protocol deviation | 6 | 2 |
| Randomization allocation unclear | 1 | 2 |
| Rejected colonoscopy | 4 | 6 |

Baseline characteristics

Reporting groups

| | |
|--|-----------------------------|
| Reporting group title | Intervention (1L PEG + Asc) |
| Reporting group description: | |
| Participants randomized to receive intervention (1L polyethylene glycol + ascorbate) | |
| Reporting group title | Control (2L PEG + Asc) |
| Reporting group description: | |
| Participants randomized to receive control (2L polyethylene glycol + ascorbate) | |

| Reporting group values | Intervention (1L PEG + Asc) | Control (2L PEG + Asc) | Total |
|---------------------------------------|-----------------------------|------------------------|-------|
| Number of subjects | 629 | 646 | 1275 |
| Age categorical Units: Subjects | | | |
| Adults (18-64 years) | 335 | 346 | 681 |
| From 65-84 years | 294 | 300 | 594 |
| Age continuous Units: years | | | |
| median | 64 | 64 | |
| inter-quartile range (Q1-Q3) | 56 to 70 | 56 to 70 | - |
| Gender categorical Units: Subjects | | | |
| Female | 322 | 310 | 632 |
| Male | 307 | 336 | 643 |

End points

End points reporting groups

| | |
|--|-----------------------------|
| Reporting group title | Intervention (1L PEG + Asc) |
| Reporting group description: | |
| Participants randomized to receive intervention (1L polyethylene glycol + ascorbate) | |
| Reporting group title | Control (2L PEG + Asc) |
| Reporting group description: | |
| Participants randomized to receive control (2L polyethylene glycol + ascorbate) | |

Primary: To evaluate the overall bowel cleansing efficacy of 1L PEG + Asc vs. 2L PEG + Asc

| | |
|---|---|
| End point title | To evaluate the overall bowel cleansing efficacy of 1L PEG + Asc vs. 2L PEG + Asc |
| End point description: | |
| Efficacy of the bowel cleansing efficacy in the two arms were determined using the Boston Bowel Preparation Scale. All participants undergoing colonoscopy were assessed. | |
| End point type | Primary |
| End point timeframe: | |
| After colonoscopy | |

| End point values | Intervention (1L PEG + Asc) | Control (2L PEG + Asc) | | |
|--------------------------------------|-----------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 615 | 628 | | |
| Units: 4 | | | | |
| arithmetic mean (standard deviation) | | | | |
| BBPS right colon | 2.54 (± 0.77) | 2.30 (± 0.90) | | |
| BBPS transverse colon | 2.60 (± 0.71) | 2.36 (± 0.87) | | |
| BBPS left colon | 2.63 (± 0.63) | 2.39 (± 0.80) | | |
| BBPS total | 7.76 (± 1.93) | 7.06 (± 2.41) | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Wilcoxon rank sum test |
| Statistical analysis description: | |
| Efficacy will be assessed as bowel cleansing success according to the validated Boston Bowel Preparation Scale (BBPS). Bowel preparation quality will be assessed by the colonoscopist for the following colonic segments: Right colon, transverse colon and left colon. After washing and suctioning have been performed each segment is given a score from 0-3. | |
| Comparison groups | Intervention (1L PEG + Asc) v Control (2L PEG + Asc) |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 1243 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 ^[1] |
| Method | Wilcoxon (Mann-Whitney) |

Notes:

[1] - Left colon, transverse colon, right colon and total scores all showed $p < 0.001$

Primary: To evaluate the bowel cleansing efficacy of 1L PEG + Asc vs. 2L PEG + Asc in terms of adequate bowel preparation

| | |
|-----------------|--|
| End point title | To evaluate the bowel cleansing efficacy of 1L PEG + Asc vs. 2L PEG + Asc in terms of adequate bowel preparation |
|-----------------|--|

End point description:

Efficacy of the bowel cleansing efficacy in the two arms were determined using the Boston Bowel Preparation Scale. All participants undergoing colonoscopy were assessed. Data were assessed for all participants with adequate bowel preparation defined as BBPS ≥ 2 in each segment.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

After colonoscopy

| End point values | Intervention (1L PEG + Asc) | Control (2L PEG + Asc) | | |
|--------------------------------------|-----------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 567 ^[2] | 541 ^[3] | | |
| Units: 4 | | | | |
| arithmetic mean (standard deviation) | | | | |
| BBPS right colon | 2.71 (\pm 0.45) | 2.59 (\pm 0.49) | | |
| BBPS transverse colon | 2.73 (\pm 0.45) | 2.63 (\pm 0.48) | | |
| BBPS left colon | 2.71 (\pm 0.45) | 2.60 (\pm 0.49) | | |
| BBPS total | 8.16 (\pm 1.23) | 7.82 (\pm 1.33) | | |

Notes:

[2] - Number of participants with a BBPS score in any segment of at least 2

[3] - Number of participants with a BBPS score in any segment of at least 2

Statistical analyses

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Wilcoxon rank sum test |
|-----------------------------------|------------------------|

Statistical analysis description:

Wilcoxon rank sum test

| | |
|---|--|
| Comparison groups | Intervention (1L PEG + Asc) v Control (2L PEG + Asc) |
| Number of subjects included in analysis | 1108 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 ^[4] |
| Method | Wilcoxon (Mann-Whitney) |

Notes:

[4] - Left colon, transverse colon, right colon and total scores all showed $p < 0.001$

Primary: To evaluate the bowel cleansing efficacy of 1L PEG + Asc vs. 2L PEG + Asc

in terms of excellent bowel preparation

| | |
|-----------------|---|
| End point title | To evaluate the bowel cleansing efficacy of 1L PEG + Asc vs. 2L PEG + Asc in terms of excellent bowel preparation |
|-----------------|---|

End point description:

Efficacy of the bowel cleansing efficacy in the two arms were determined using the Boston Bowel Preparation Scale. All participants undergoing colonoscopy were assessed. Data were assessed for all participants with excellent bowel preparation in each segment (BBPS =3)

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

After colonoscopy

| End point values | Intervention (1L PEG + Asc) | Control (2L PEG + Asc) | | |
|-----------------------------|--------------------------------|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 613 | 627 | | |
| Units: Number BBPS = 3 | | | | |
| Right colon | 405 | 319 | | |
| Transverse colon | 420 | 345 | | |
| Left colon | 421 | 336 | | |

Statistical analyses

| | |
|----------------------------|------------|
| Statistical analysis title | Chi square |
|----------------------------|------------|

Statistical analysis description:

Number of participants with a BBPS score in any segment of 3

| | |
|---|--|
| Comparison groups | Intervention (1L PEG + Asc) v Control (2L PEG + Asc) |
| Number of subjects included in analysis | 1240 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 ^[5] |
| Method | Chi-squared |

Notes:

[5] - Left colon, transverse colon, right colon and overall scores all showed p<0.001

Secondary: Adenoma detection rate

| | |
|-----------------|------------------------|
| End point title | Adenoma detection rate |
|-----------------|------------------------|

End point description:

Data on adenomas were obtained from histopathologic reports. In case of large lesions planned for subsequent polypectomy or participants on anticoagulation/antiplatelet medication a subsequent colonoscopy was performed and data from these procedures were included as well.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

During colonoscopy

| End point values | Intervention (1L PEG + Asc) | Control (2L PEG + Asc) | | |
|-----------------------------|-----------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 615 | 628 | | |
| Units: % | | | | |
| Adenoma detection rate | 50 | 48 | | |

Statistical analyses

| | |
|--|--|
| Statistical analysis title | Chi square |
| Statistical analysis description: | |
| Number of participants where at least one adenoma was detected | |
| Comparison groups | Intervention (1L PEG + Asc) v Control (2L PEG + Asc) |
| Number of subjects included in analysis | 1243 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.5 |
| Method | Chi-squared |

Secondary: Cancer detection

| | |
|--|------------------|
| End point title | Cancer detection |
| End point description: | |
| Data on adenomas were obtained from histopathologic reports. In case of large lesions planned for subsequent polypectomy or participants on anticoagulation/antiplatelet medication a subsequent colonoscopy was performed and data from these procedures were included as well. | |
| End point type | Secondary |
| End point timeframe: | |
| During colonoscopy | |

| End point values | Intervention (1L PEG + Asc) | Control (2L PEG + Asc) | | |
|-----------------------------|-----------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 615 | 628 | | |
| Units: number | | | | |
| Number of cancers | 27 | 24 | | |

Statistical analyses

| | |
|--|--|
| Statistical analysis title | Chi square |
| Statistical analysis description: | |
| Number of participants detected with colorectal cancer | |
| Comparison groups | Intervention (1L PEG + Asc) v Control (2L PEG + Asc) |

| | |
|---|---------------|
| Number of subjects included in analysis | 1243 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.7 |
| Method | Chi-squared |

Secondary: Serrated lesion detection rate

| | |
|--|--------------------------------|
| End point title | Serrated lesion detection rate |
| End point description: Data on adenomas were obtained from histopathologic reports. In case of large lesions planned for subsequent polypectomy or participants on anticoagulation/antiplatelet medication a subsequent colonoscopy was performed and data from these procedures were included as well. | |
| End point type | Secondary |
| End point timeframe: During colonoscopy | |

| End point values | Intervention (1L PEG + Asc) | Control (2L PEG + Asc) | | |
|------------------------------------|-----------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 615 | 628 | | |
| Units: % | | | | |
| Serrated lesion detection rate (%) | 16 | 15 | | |

Statistical analyses

| | |
|--|--|
| Statistical analysis title | Chi square |
| Statistical analysis description: Rate of participants with at least one serrated lesion detected | |
| Comparison groups | Intervention (1L PEG + Asc) v Control (2L PEG + Asc) |
| Number of subjects included in analysis | 1243 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.6 |
| Method | Chi-squared |

Secondary: Tolerability of the bowel preparation, nausea

| | |
|---|---|
| End point title | Tolerability of the bowel preparation, nausea |
| End point description: Participants were asked to answer a questionnaire when arriving at the endoscopy unit, but prior to colonoscopy | |
| End point type | Secondary |

End point timeframe:

Prior to colonoscopy

| End point values | Intervention (1L PEG + Asc) | Control (2L PEG + Asc) | | |
|-----------------------------|--------------------------------|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 599 | 618 | | |
| Units: Condition present, % | | | | |
| Nausea | 344 | 288 | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Chi square |
| Statistical analysis description: | |
| Number of participants reporting any nausea | |
| Comparison groups | Intervention (1L PEG + Asc) v Control (2L PEG + Asc) |
| Number of subjects included in analysis | 1217 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Chi-squared |

Secondary: Tolerability of the bowel preparation, vomit

| | |
|---|--|
| End point title | Tolerability of the bowel preparation, vomit |
| End point description: | |
| Participants were asked to answer a questionnaire when arriving at the endoscopy unit, but prior to colonoscopy | |
| End point type | Secondary |
| End point timeframe: | |
| Prior to colonoscopy | |

| End point values | Intervention (1L PEG + Asc) | Control (2L PEG + Asc) | | |
|-----------------------------|--------------------------------|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 599 | 618 | | |
| Units: Condition present, % | | | | |
| Vomit | 83 | 54 | | |

Statistical analyses

| | |
|--|--|
| Statistical analysis title | Chi square |
| Statistical analysis description: | |
| Number of participants reporting of any comiting | |
| Comparison groups | Intervention (1L PEG + Asc) v Control (2L PEG + Asc) |
| Number of subjects included in analysis | 1217 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.006 |
| Method | Chi-squared |

Secondary: Tolerability of the bowel preparation, bloating

| | |
|---|---|
| End point title | Tolerability of the bowel preparation, bloating |
| End point description: | |
| Participants were asked to answer a questionnaire when arriving at the endoscopy unit, but prior to colonoscopy | |
| End point type | Secondary |
| End point timeframe: | |
| Prior to colonoscopy | |

| End point values | Intervention (1L PEG + Asc) | Control (2L PEG + Asc) | | |
|-----------------------------|--------------------------------|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 599 | 618 | | |
| Units: Condition present, % | | | | |
| Bloating | 382 | 420 | | |

Statistical analyses

| | |
|--|--|
| Statistical analysis title | Chi square |
| Statistical analysis description: | |
| Number of participants reporting of any bloating | |
| Comparison groups | Intervention (1L PEG + Asc) v Control (2L PEG + Asc) |
| Number of subjects included in analysis | 1217 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.14 |
| Method | Chi-squared |

Secondary: Tolerability of the bowel preparation, headache

| | |
|-----------------|---|
| End point title | Tolerability of the bowel preparation, headache |
|-----------------|---|

End point description:

Participants were asked to answer a questionnaire when arriving at the endoscopy unit, but prior to colonoscopy

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Prior to colonoscopy

| End point values | Intervention (1L PEG + Asc) | Control (2L PEG + Asc) | | |
|-----------------------------|--------------------------------|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 599 | 618 | | |
| Units: Condition present, % | | | | |
| Headache | 214 | 188 | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Chi square |
| Comparison groups | Intervention (1L PEG + Asc) v Control (2L PEG + Asc) |
| Number of subjects included in analysis | 1217 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.057 |
| Method | Chi-squared |

Secondary: Tolerability of the bowel preparation, sleep interrupted

| | |
|-----------------|--|
| End point title | Tolerability of the bowel preparation, sleep interrupted |
|-----------------|--|

End point description:

Participants were asked to answer a questionnaire when arriving at the endoscopy unit, but prior to colonoscopy

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Prior to colonoscopy

| End point values | Intervention (1L PEG + Asc) | Control (2L PEG + Asc) | | |
|-----------------------------|--------------------------------|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 599 | 618 | | |
| Units: Condition present, % | | | | |
| Sleep interrupted | 358 | 376 | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Chi square |
| Statistical analysis description: | |
| Number of participants reporting any disturbance of sleep | |
| Comparison groups | Intervention (1L PEG + Asc) v Control (2L PEG + Asc) |
| Number of subjects included in analysis | 1217 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.7 |
| Method | Chi-squared |

Secondary: Tolerability of the bowel preparation, willingness to repeat

| | |
|---|--|
| End point title | Tolerability of the bowel preparation, willingness to repeat |
| End point description: | |
| Participants were asked to answer a questionnaire when arriving at the endoscopy unit, but prior to colonoscopy | |
| End point type | Secondary |
| End point timeframe: | |
| Prior to colonoscopy | |

| End point values | Intervention (1L PEG + Asc) | Control (2L PEG + Asc) | | |
|-----------------------------|-----------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 599 | 618 | | |
| Units: Condition present, % | | | | |
| Willingness to repeat | 492 | 469 | | |

Statistical analyses

| | |
|--|--|
| Statistical analysis title | Chi square |
| Statistical analysis description: | |
| Number of participants reporting willingness to repeat the bowel cleansing | |
| Comparison groups | Intervention (1L PEG + Asc) v Control (2L PEG + Asc) |
| Number of subjects included in analysis | 1217 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.009 |
| Method | Chi-squared |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day and time of colonoscopy for participants reported events

30 day follow up for complications

Adverse event reporting additional description:

Participants were asked to answer a questionnaire when arriving at the endoscopy unit, but prior to colonoscopy. This questionnaire included information about any adverse events/side effects other than asked in the questionnaire (nausea, vomit, bloating, headache and disturbance of sleep). A file look-up was made to evaluate 30 day complications.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|------|
| Dictionary name | None |
|-----------------|------|

| | |
|--------------------|---------|
| Dictionary version | unknown |
|--------------------|---------|

Reporting groups

| | |
|-----------------------|--------------|
| Reporting group title | 1L PEG + Asc |
|-----------------------|--------------|

Reporting group description: -

| | |
|-----------------------|--------------|
| Reporting group title | 2L PEG + Asc |
|-----------------------|--------------|

Reporting group description: -

| Serious adverse events | 1L PEG + Asc | 2L PEG + Asc | |
|---|-----------------|-----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 615 (0.00%) | 0 / 628 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |

Frequency threshold for reporting non-serious adverse events: 0.1 %

| Non-serious adverse events | 1L PEG + Asc | 2L PEG + Asc | |
|---|-------------------|------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 75 / 615 (12.20%) | 56 / 628 (8.92%) | |
| Nervous system disorders | | | |
| Dizziness | | | |
| subjects affected / exposed | 7 / 615 (1.14%) | 4 / 628 (0.64%) | |
| occurrences (all) | 7 | 4 | |
| Fatigue | | | |
| subjects affected / exposed | 5 / 615 (0.81%) | 3 / 628 (0.48%) | |
| occurrences (all) | 5 | 3 | |
| Headache | | | |

| | | | |
|---|----------------------|------------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 615 (0.00%) 0 | 2 / 628 (0.32%) 2 | |
| General disorders and administration site conditions | | | |
| Freezing | | | |
| subjects affected / exposed occurrences (all) | 1 / 615 (0.16%) 1 | 0 / 628 (0.00%) 0 | |
| Non function | | | |
| subjects affected / exposed occurrences (all) | 1 / 615 (0.16%) 1 | 0 / 628 (0.00%) 0 | |
| Unrest | | | |
| subjects affected / exposed occurrences (all) | 2 / 615 (0.33%) 2 | 3 / 628 (0.48%) 3 | |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed occurrences (all) | 2 / 615 (0.33%) 2 | 18 / 628 (2.87%) 18 | |
| Bloating | | | |
| subjects affected / exposed occurrences (all) | 4 / 615 (0.65%) 4 | 6 / 628 (0.96%) 6 | |
| Constipation | | | |
| subjects affected / exposed occurrences (all) | 0 / 615 (0.00%) 0 | 1 / 628 (0.16%) 1 | |
| Diarrhoea | | | |
| subjects affected / exposed occurrences (all) | 2 / 615 (0.33%) 2 | 0 / 628 (0.00%) 0 | |
| Dry mouth | | | |
| subjects affected / exposed occurrences (all) | 1 / 615 (0.16%) 1 | 0 / 628 (0.00%) 0 | |
| Fecal incontinence | | | |
| subjects affected / exposed occurrences (all) | 2 / 615 (0.33%) 2 | 1 / 628 (0.16%) 1 | |
| Nausea | | | |
| subjects affected / exposed occurrences (all) | 3 / 615 (0.49%) 3 | 1 / 628 (0.16%) 1 | |
| Vomiting | | | |

| | | | |
|--|--|--|--|
| subjects affected / exposed occurrences (all) | 1 / 615 (0.16%) 1 | 0 / 628 (0.00%) 0 | |
| Respiratory, thoracic and mediastinal disorders Flu subjects affected / exposed occurrences (all) | 3 / 615 (0.49%) 3 | 0 / 628 (0.00%) 0 | |
| Skin and subcutaneous tissue disorders Anal discomfort subjects affected / exposed occurrences (all) Rash subjects affected / exposed occurrences (all) | 14 / 615 (2.28%) 14 1 / 615 (0.16%) 1 | 5 / 628 (0.80%) 5 0 / 628 (0.00%) 0 | |
| Musculoskeletal and connective tissue disorders Groin pain subjects affected / exposed occurrences (all) Malaise subjects affected / exposed occurrences (all) | 1 / 615 (0.16%) 1 1 / 615 (0.16%) 1 | 0 / 628 (0.00%) 0 0 / 628 (0.00%) 0 | |
| Infections and infestations Fever subjects affected / exposed occurrences (all) Freezing subjects affected / exposed occurrences (all) | 1 / 615 (0.16%) 1 11 / 615 (1.79%) 11 | 1 / 628 (0.16%) 1 9 / 628 (1.43%) 9 | |
| Metabolism and nutrition disorders Poor palatability subjects affected / exposed occurrences (all) Thirst subjects affected / exposed occurrences (all) | 2 / 615 (0.33%) 2 11 / 615 (1.79%) 11 | 2 / 628 (0.32%) 2 0 / 628 (0.00%) 0 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported