



Clinical trial results:

Efficacy, Safety and Tolerability of CitraFleet, a New Bowel Cleansing Agent – a Prospective, Single-Center, Single-Group Phase IV Study Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2018-003257-16 |
| Trial protocol | HU |
| Global end of trial date | 17 December 2019 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 03 June 2021 |
| First version publication date | 03 June 2021 |

Trial information

Trial identification

| | |
|-----------------------|-------------------|
| Sponsor protocol code | CitraFleet_H-2018 |
|-----------------------|-------------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|-------------------------------------------------------------------------------|
| Sponsor organisation name | Goodwill Pharma Kft |
| Sponsor organisation address | Cserzy Mihály u. 32., Szeged, Hungary, 6724 |
| Public contact | DQPPV, Goodwill Pharma Kft, 36 704522104, janoska.zsolt@goodwillpharma.com |
| Scientific contact | DQPPV, Goodwill Pharma Kft, 36 704522104, janoska.zsolt@goodwillpharma.com |

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 | 17 December 2019 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 17 December 2019 |
| Global end of trial reached? | Yes |
| Global end of trial date | 17 December 2019 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To measure efficacy of CitraFleet by using Boston Bowel Preparation Scale.

Protection of trial subjects:

The Investigators will ensure that the patient is given full and adequate oral and written information about the nature, purpose, possible risk and benefit of the study. Patients must also be notified that they are free to discontinue from the study at any time. The patient should be given the opportunity to ask questions and allowed time to consider the information provided. The patient's signed and dated informed consent must be obtained before conducting any procedure specifically for the study.

Background therapy:

Patients scheduled to undergo colonoscopy

Evidence for comparator:

NA single group study

| | |
|-----------------------------------------------------------|-----------------|
| Actual start date of recruitment | 15 January 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 | Hungary: 93 |
| Worldwide total number of subjects | 93 |
| EEA total number of subjects | 93 |

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) | 73 |
| From 65 to 84 years | 20 |

| | |
|-------------------|---|
| 85 years and over | 0 |
|-------------------|---|

Subject disposition

Recruitment

Recruitment details:

Recruitment started on 25th March 2019 and last patient last visit took place on 31st October 2019. Patients were enrolled at a single study site (Colonoscopy Unit, Department of Internal Medicine No. I., University of Szeged)

Pre-assignment

Screening details:

A total of 100 patients were screened, 93 were treated and enrolled to the study.

Period 1

| | |
|------------------------------|-----------------------------|
| Period 1 title | Colonoscopy |
| Is this the baseline period? | Yes |
| Allocation method | Non-randomised - controlled |
| Blinding used | Not blinded |

Blinding implementation details:

NA no blinding

Arms

| | |
|-----------|--------------|
| Arm title | All patients |
|-----------|--------------|

Arm description:

All patients treated

| | |
|----------------------------------------|------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | CitraFleet por belsőleges oldathoz |
| Investigational medicinal product code | A06AB58 |
| Other name | |
| Pharmaceutical forms | Powder for oral solution in sachet |
| Routes of administration | Oral use |

Dosage and administration details:

30 g administered according to approved Summary of Product Characteristics.

| | |
|---------------------------------------|--------------|
| Number of subjects in period 1 | All patients |
| Started | 93 |
| Completed | 93 |

Period 2

| | |
|------------------------------|----------------|
| Period 2 title | Screening |
| Is this the baseline period? | No |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|----------------------------------------|------------------------------------|
| Arm title | All patients |
| Arm description: | |
| All patients treated | |
| Arm type | Experimental |
| Investigational medicinal product name | CitraFleet por belsőleges oldathoz |
| Investigational medicinal product code | A06AB58 |
| Other name | |
| Pharmaceutical forms | Powder for oral solution in sachet |
| Routes of administration | Oral use |

Dosage and administration details:

30 g administered according to approved Summary of Product Characteristics.

| | |
|---------------------------------------|--------------|
| Number of subjects in period 2 | All patients |
| Started | 93 |
| Completed | 93 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|-------------|
| Reporting group title | Colonoscopy |
|-----------------------|-------------|

Reporting group description: -

| Reporting group values | Colonoscopy | Total | |
|-------------------------------------------------------|-------------|-------|--|
| Number of subjects | 93 | 93 | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 73 | 73 | |
| From 65-84 years | 20 | 20 | |
| 85 years and over | 0 | 0 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 51 | 51 | |
| Male | 42 | 42 | |

End points

End points reporting groups

| | |
|------------------------------|--------------|
| Reporting group title | All patients |
| Reporting group description: | |
| All patients treated | |
| Reporting group title | All patients |
| Reporting group description: | |
| All patients treated | |

Primary: Boston Bowel Preparation Scale

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| End point title | Boston Bowel Preparation Scale ^[1] |
| End point description: | |
| The efficacy of Citrafleet will be measured using the Boston Bowel Preparation Scale by the ratio of patients achieving appropriate cleaning. An overall score of 6-9, with a score of at least 2 in each colon segment will be considered appropriate cleaning, a score of 0-5, or any segmental score below 2 means that the preparation method was unsatisfactory. | |
| End point type | Primary |
| End point timeframe: | |
| Assessed by the Investigator during endoscopy procedure. | |
| Notes: | |
| [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. | |
| Justification: No formal hypothesis testing | |

| | | | | |
|--------------------------------------------|-----------------|--|--|--|
| End point values | All patients | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 93 | | | |
| Units: patients | | | | |
| ratio of atients with appropriate cleaning | 85 | | | |
| incomplete examination | 5 | | | |
| ineffective bowel preparation | 3 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Safety by serum Na values

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| End point title | Safety by serum Na values |
| End point description: | |
| For each laboratory parameter number and frequency of the above categories will be given by timepoint (i.e. at screening and at colonoscopy). | |
| End point type | Secondary |
| End point timeframe: | |
| For each laboratory parameter number and frequency of the above categories will be given by timepoint (i.e. at screening and at colonoscopy). | |

| | | | | |
|-----------------------------|-----------------|-----------------|--|--|
| End point values | All patients | All patients | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 93 | 93 | | |
| Units: patients | | | | |
| normal | 92 | 91 | | |
| abnormal, not significant | 1 | 2 | | |
| abnormal significant | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Safety by serum K values

| | |
|-----------------|--------------------------|
| End point title | Safety by serum K values |
|-----------------|--------------------------|

End point description:

Laboratory parameters will be categorized as
normal,
abnormal, clinically not significant,
abnormal, clinically significant.

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

End point timeframe:

For each laboratory parameter number and frequency of the above categories will be given by
timepoint (i.e. at screening and at colonoscopy).

| | | | | |
|---------------------------------------|-----------------|-----------------|--|--|
| End point values | All patients | All patients | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 93 | 93 | | |
| Units: patients | | | | |
| normal | 89 | 87 | | |
| abnormal, clinically not significant, | 4 | 6 | | |
| abnormal, clinically significant. | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Na values descriptive statistics

| | |
|-----------------|----------------------------------------|
| End point title | Serum Na values descriptive statistics |
|-----------------|----------------------------------------|

End point description:

The change in continuous laboratory parameter values will be analyzed using
descriptive statistics (mean, standard deviation, median, minimum and maximum).

| | |
|------------------------------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: screening and at colonoscopy | |

| | | | | |
|--------------------------------------|----------------------|-------------------|--|--|
| End point values | All patients | All patients | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 93 | 93 | | |
| Units: mmol/l | | | | |
| arithmetic mean (standard deviation) | 140.53 (\pm 1.96) | 139 (\pm 1.96) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Serum K values descriptive statistics

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| End point title | Serum K values descriptive statistics |
| End point description: The change in continuous laboratory parameter values will be analyzed using descriptive statistics (mean, standard deviation, median, minimum and maximum) | |
| End point type | Secondary |
| End point timeframe: screening and at colonoscopy | |

| | | | | |
|--------------------------------------|--------------------|--------------------|--|--|
| End point values | All patients | All patients | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 93 | 93 | | |
| Units: mmol/l | | | | |
| arithmetic mean (standard deviation) | 4.43 (\pm 0.38) | 4.29 (\pm 0.36) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Serum urea categorical

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| End point title | Serum urea categorical |
| End point description: Laboratory parameters will be categorized as normal, abnormal, clinically not significant, abnormal, clinically significant. | |
| End point type | Secondary |

End point timeframe:
screening and at colonoscopy

| End point values | All patients | All patients | | |
|---------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 93 | 93 | | |
| Units: patients | | | | |
| normal | 89 | 87 | | |
| abnormal, clinically not significant, | 4 | 6 | | |
| abnormal, clinically significant | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Serum urea descriptive

End point title Serum urea descriptive

End point description:

The change in continuous laboratory parameter values will be analyzed using descriptive statistics (mean, standard deviation, median, minimum and maximum).

End point type Secondary

End point timeframe:

screening and at colonoscopy

| End point values | All patients | All patients | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 93 | 93 | | |
| Units: mmol/l | | | | |
| arithmetic mean (standard deviation) | 4.60 (± 1.36) | 3.30 (± 1.07) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Serum creatinine categorical

End point title Serum creatinine categorical

End point description:

Laboratory parameters will be categorized as
normal,
abnormal, clinically not significant,
abnormal, clinically significant.

| | |
|------------------------------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: screening and at colonoscopy | |

| End point values | All patients | All patients | | |
|---------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 93 | 93 | | |
| Units: patients | | | | |
| normal | 87 | 87 | | |
| abnormal, clinically not significant, | 6 | 6 | | |
| abnormal, clinically significant | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Serum creatinine descriptive

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| End point title | Serum creatinine descriptive |
| End point description: The change in continuous laboratory parameter values will be analyzed using descriptive statistics (mean, standard deviation, median, minimum and maximum). | |
| End point type | Secondary |
| End point timeframe: screening and at colonoscopy | |

| End point values | All patients | All patients | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 93 | 93 | | |
| Units: mmol/l | | | | |
| arithmetic mean (standard deviation) | 73.64 (± 14.22) | 76.41 (± 13.92) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Overall tolerability (VAS scale)

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| End point title | Overall tolerability (VAS scale) |
| End point description: The overall tolerability (based on the VAS scale) will be described by the mean, median, minimum and maximum values. | |

| | |
|-------------------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: after colonoscopy | |

| | | | | |
|----------------------------------------|-----------------|--|--|--|
| End point values | All patients | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 93 | | | |
| Units: NA | | | | |
| arithmetic mean (full range (min-max)) | 8.48 (1 to 10) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Patient opinion on taste

| | |
|--------------------------------------------------------------|--------------------------|
| End point title | Patient opinion on taste |
| End point description: Patient tolerability questionnaire | |
| End point type | Secondary |
| End point timeframe: after colonoscopy | |

| | | | | |
|-----------------------------|-----------------|--|--|--|
| End point values | All patients | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 93 | | | |
| Units: patients | | | | |
| normal | 83 | | | |
| medium symptoms | 3 | | | |
| severe symptoms | 7 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Patient opinion on excessive thirst

| | |
|------------------------------------------------------------------|-------------------------------------|
| End point title | Patient opinion on excessive thirst |
| End point description: Via patient tolerability questionnaire | |
| End point type | Secondary |

End point timeframe:

After colonoscopy

| | | | | |
|-----------------------------|-----------------|--|--|--|
| End point values | All patients | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 93 | | | |
| Units: patients | | | | |
| normal | 90 | | | |
| medium symptoms | 3 | | | |
| severe symptoms | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Patient opinion on nausea

| | |
|------------------------------------------------------------------|---------------------------|
| End point title | Patient opinion on nausea |
| End point description: via patient tolerability questionnaire | |
| End point type | Secondary |
| End point timeframe: after colonoscopy | |

| | | | | |
|-----------------------------|-----------------|--|--|--|
| End point values | All patients | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 93 | | | |
| Units: patients | | | | |
| normal | 88 | | | |
| medium symptoms | 4 | | | |
| severe symptoms | 1 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Patient feedback on bloating

| | |
|----------------------------------------------------------|------------------------------|
| End point title | Patient feedback on bloating |
| End point description: via tolerability questionnaire | |
| End point type | Secondary |

End point timeframe:
after colonoscopy

| | | | | |
|-----------------------------|-----------------|--|--|--|
| End point values | All patients | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 93 | | | |
| Units: patients | | | | |
| normal | 87 | | | |
| medium symptoms | 6 | | | |
| severe symptoms | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Patient feedback on abdominal pain and cramps

| | |
|------------------------|-----------------------------------------------|
| End point title | Patient feedback on abdominal pain and cramps |
| End point description: | via patient tolerability questionnaire |
| End point type | Secondary |
| End point timeframe: | after colonoscopy |

| | | | | |
|-----------------------------|-----------------|--|--|--|
| End point values | All patients | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 93 | | | |
| Units: patients | | | | |
| normal | 83 | | | |
| medium symptoms | 10 | | | |
| severe symptoms | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Patient feedback on headache

| | |
|------------------------|----------------------------------------|
| End point title | Patient feedback on headache |
| End point description: | via patient tolerability questionnaire |
| End point type | Secondary |

End point timeframe:
after colonoscopy

| | | | | |
|-----------------------------|-----------------|--|--|--|
| End point values | All patients | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 93 | | | |
| Units: patients | | | | |
| normal | 89 | | | |
| medium symptoms | 4 | | | |
| severe symptoms | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Patient feedback on dizziness

| | |
|------------------------------------------------------------------|-------------------------------|
| End point title | Patient feedback on dizziness |
| End point description: via patient tolerability questionnaire | |
| End point type | Secondary |
| End point timeframe: after colonoscopy | |

| | | | | |
|-----------------------------|-----------------|--|--|--|
| End point values | All patients | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 93 | | | |
| Units: patients | | | | |
| normal | 91 | | | |
| medium symptoms | 1 | | | |
| severe symptoms | 1 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Patient feedback on sleep disturbance

| | |
|------------------------------------------------------------------|---------------------------------------|
| End point title | Patient feedback on sleep disturbance |
| End point description: via patient tolerability questionnaire | |
| End point type | Secondary |

End point timeframe:
after colonoscopy

| | | | | |
|-----------------------------|-----------------|--|--|--|
| End point values | All patients | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 93 | | | |
| Units: patients | | | | |
| normal | 91 | | | |
| medium symptoms | 2 | | | |
| severe symptoms | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events are reported from screening until end of colonoscopy procedure (end-of-study).

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

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 10.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-------------------|
| Reporting group title | Safety population |
|-----------------------|-------------------|

Reporting group description:

Safety population consists of all patients who were involved in the study and received the study medication.

| Serious adverse events | Safety population | | |
|---------------------------------------------------|-------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 93 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |

Frequency threshold for reporting non-serious adverse events: 0 %

| Non-serious adverse events | Safety population | | |
|-------------------------------------------------------|-------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 67 / 93 (72.04%) | | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 17 / 93 (18.28%) | | |
| occurrences (all) | 17 | | |
| Dizziness | | | |
| subjects affected / exposed | 16 / 93 (17.20%) | | |
| occurrences (all) | 16 | | |
| Sleep disorder | | | |
| subjects affected / exposed | 20 / 93 (21.51%) | | |
| occurrences (all) | 20 | | |
| Gastrointestinal disorders | | | |

| | | | |
|------------------------------------|------------------|--|--|
| Flatulence | | | |
| subjects affected / exposed | 30 / 93 (32.26%) | | |
| occurrences (all) | 30 | | |
| Abdominal pain | | | |
| subjects affected / exposed | 36 / 93 (38.71%) | | |
| occurrences (all) | 36 | | |
| Metabolism and nutrition disorders | | | |
| Thirst | | | |
| subjects affected / exposed | 29 / 93 (31.18%) | | |
| occurrences (all) | 29 | | |
| Nausea | | | |
| subjects affected / exposed | 23 / 93 (24.73%) | | |
| occurrences (all) | 23 | | |

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