



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 (\pm 1.36)	3.30 (\pm 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 tolerabilty 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