Clinical trial results:
A Phase 1 Crossover Study to Assess the Relative Bioavailability of Roxadustat Following a Single Dose of Pediatric Azo Dye-free Tablet and Pediatric Azo Dye-free Mini-tablet (Solid and Suspension) Compared to a Single Dose of Azo Dye-containing Tablet in Healthy Adult Subjects

Summary

EudraCT number	2018-002924-18
Trial protocol	DE
Global end of trial date	14 October 2019

Results information

Result version number	v1 (current)
This version publication date	09 October 2020
First version publication date	09 October 2020

Trial information

Trial identification

Sponsor protocol code	1517-CL-1001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03960489
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Astellas Pharma Global Development, Inc. (APGD)
Sponsor organisation address	1 Astellas Way, Northbrook, IL, United States, 60062
Public contact	Clinical Trial Disclosure, Astellas Pharma Global Development, Inc. (APGD), 31 71 5455 050, astellas.resultsdisclosure@astellas.com
Scientific contact	Clinical Trial Disclosure, Astellas Pharma Global Development, Inc. (APGD), 31 71 5455 050, astellas.resultsdisclosure@astellas.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001557-PIP01-13
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	14 October 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 October 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study was to assess the relative bioavailability of single doses of 100 mg roxadustat pediatric azo dye-free tablet and 100 mg roxadustat pediatric azo dye-free mini-tablet solid and suspension (new formulations) compared to 100 mg roxadustat azo dye-containing tablet (reference formulation) under fasting conditions in healthy male and female adult participants.

Protection of trial subjects:

This clinical study was written, conducted and reported in accordance with the protocol, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guidelines, and applicable local regulations, including the European Directive 2001/20/EC, on the protection of human rights, and with the ethical principles that have their origin in the Declaration of Helsinki. Astellas ensures that the use and disclosure of protected health information (PHI) obtained during a research study complies with the federal, national and/or regional legislation related to the privacy and protection of personal information.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 July 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	Germany: 24
Worldwide total number of subjects	24
EEA total number of subjects	24

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)	24
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled in one site in Germany.

Pre-assignment

Screening details:

Participants were randomized in 1:1:1:1 ratio to 1 of 4 treatment sequence in the study. Each participant participated in 4 treatment periods separated by a washout of at least 7 days.

Period 1

Period 1 title	Treatment Period 1 (6 days)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Treatment Sequence 1 (ABCD)

Arm description:

Participants received single dose of 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 3 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	Experimental
Investigational medicinal product name	Roxadustat 100 mg azo dye free tablet/mini tablet suspension/solid mini tablet/dye containing tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension, Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg roxadustat pediatric azo dye-free tablet or dye free mini tablet suspension or dye free solid mini tablet or dye containing tablet as per the dosing sequence.

Arm title	Treatment Sequence 2 (BDAC)

Arm description:

Particpants received 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 1 followed by single dose of 100 mg of roxadustat azo dye-containing tablet (D), orally on day 1 in period 2 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	Experimental
Investigational medicinal product name	Roxadustat 100 mg azo dye free tablet/mini tablet suspension/solid mini tablet/dye containing tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension, Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg roxadustat pediatric azo dye-free tablet or dye free mini tablet suspension or dye free solid mini tablet or dye containing tablet as per the dosing sequence.

Arm title	Treatment Sequence 3 (CADB)

Arm description:

Participants received 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 1 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 2 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	Experimental
Investigational medicinal product name	Roxadustat 100 mg azo dye free tablet/mini tablet suspension/solid mini tablet/dye containing tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension, Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg roxadustat pediatric azo dye-free tablet or dye free mini tablet suspension or dye free solid mini tablet or dye containing tablet as per the dosing sequence.

Arm title	Treatment Sequence 4 (DCBA)

Arm description:

Participants received single dose of 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 3 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	Experimental
Investigational medicinal product name	Roxadustat 100 mg azo dye free tablet/mini tablet suspension/solid mini tablet/dye containing tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension, Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg roxadustat pediatric azo dye-free tablet or dye free mini tablet suspension or dye free solid mini tablet or dye containing tablet as per the dosing sequence.

Number of subjects in period 1	Treatment Sequence 1 (ABCD)	Treatment Sequence 2 (BDAC)	Treatment Sequence 3 (CADB)
Started	6	6	6
Completed	6	6	6
Not completed	0	0	0
Withdrawal by subject	-	-	-

Number of subjects in period 1	Treatment Sequence 4 (DCBA)
Started	6
Completed	5
Not completed	1
Withdrawal by subject	1

Period 2

Period 2 title	Washout Period 1 (7 days)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Treatment Sequence 1 (ABCD)

Arm description:

Participants received single dose of 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 3 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Treatment Sequence 2 (BDAC)

Arm description:

Particpants received 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 1 followed by single dose of 100 mg of roxadustat azo dye-containing tablet (D), orally on day 1 in period 2 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Treatment Sequence 3 (CADB)

Arm description:

Participants received single dose of 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 1 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 2 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Treatment Sequence 4 (DCBA)

Arm description:

Participants received single dose of 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 3 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2	Treatment Sequence 1 (ABCD)	Treatment Sequence 2 (BDAC)	Treatment Sequence 3 (CADB)
Started	6	6	6
Completed	6	6	6

Number of subjects in period 2	Treatment Sequence 4 (DCBA)

Started	5
Completed	5

Period 3

Period 3 title	Treatment Period 2 (6 days)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Treatment Sequence 1 (ABCD)

Arm description:

Participants received single dose of 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 3 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	Experimental
Investigational medicinal product name	Roxadustat 100 mg azo dye free tablet/mini tablet suspension/solid mini tablet/dye containing tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension, Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg roxadustat pediatric azo dye-free tablet or dye free mini tablet suspension or dye free solid mini tablet or dye containing tablet as per the dosing sequence.

Arm title	Treatment Sequence 2 (BDAC)

Arm description:

Particpants received 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 1 followed by single dose of 100 mg of roxadustat azo dye-containing tablet (D), orally on day 1 in period 2 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	Experimental
Investigational medicinal product name	Roxadustat 100 mg azo dye free tablet/mini tablet suspension/solid mini tablet/dye containing tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension, Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg roxadustat pediatric azo dye-free tablet or dye free mini tablet suspension or dye free solid mini tablet or dye containing tablet as per the dosing sequence.

Arm title	Treatment Sequence 3 (CADB)

Arm description:

Participants received single dose of 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 1 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 2 followed by single dose of 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	Experimental
Investigational medicinal product name	Roxadustat 100 mg azo dye free tablet/mini tablet suspension/solid mini tablet/dye containing tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension, Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg roxadustat pediatric azo dye-free tablet or dye free mini tablet suspension or dye free solid mini tablet or dye containing tablet as per the dosing sequence.

Arm title	Treatment Sequence 4 (DCBA)

Arm description:

Participants received single dose of 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 3 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	Experimental
Investigational medicinal product name	Roxadustat 100 mg azo dye free tablet/mini tablet suspension/solid mini tablet/dye containing tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension, Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg roxadustat pediatric azo dye-free tablet or dye free mini tablet suspension or dye free solid mini tablet or dye containing tablet as per the dosing sequence.

Number of subjects in period 3	Treatment Sequence 1 (ABCD)	Treatment Sequence 2 (BDAC)	Treatment Sequence 3 (CADB)
Started	6	6	6
Completed	6	6	6

Number of subjects in period 3	Treatment Sequence 4 (DCBA)
Started	5
Completed	5

Period 4

Period 4 title	Washout Period 2 (7 days)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Treatment Sequence 1 (ABCD)

Arm description:

Participants received single dose of 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 3 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Treatment Sequence 2 (BDAC)

Arm description:

Particpants received 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 1 followed by single dose of 100 mg of roxadustat azo dye-containing tablet (D), orally on day 1 in period 2 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Treatment Sequence 3 (CADB)

Arm description:

Participants received single dose of 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 1 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 2 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Treatment Sequence 4 (CADB)

Arm description:

Participants received single dose of 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 3 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 4	Treatment Sequence 1 (ABCD)	Treatment Sequence 2 (BDAC)	Treatment Sequence 3 (CADB)
Started	6	6	6
Completed	6	6	6

Number of subjects in period 4	Treatment Sequence 4 (CADB)

Started	5
Completed	5

Period 5

Period 5 title	Treatment Period 3 (6 days)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Treatment Sequence 1 (ABCD)

Arm description:

Participants received single dose of 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 3 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	Experimental
Investigational medicinal product name	Roxadustat 100 mg azo dye free tablet/mini tablet suspension/solid mini tablet/dye containing tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension, Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg roxadustat pediatric azo dye-free tablet or dye free mini tablet suspension or dye free solid mini tablet or dye containing tablet as per the dosing sequence.

Arm title	Treatment Sequence 2 (BDAC)

Arm description:

Particpants received 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 1 followed by single dose of 100 mg of roxadustat azo dye-containing tablet (D), orally on day 1 in period 2 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	Experimental
Investigational medicinal product name	Roxadustat 100 mg azo dye free tablet/mini tablet suspension/solid mini tablet/dye containing tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension, Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg roxadustat pediatric azo dye-free tablet or dye free mini tablet suspension or dye free solid mini tablet or dye containing tablet as per the dosing sequence.

Arm title	Treatment Sequence 3 (CADB)

Arm description:

Participants received single dose of 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 1 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 2 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	Experimental
Investigational medicinal product name	Roxadustat 100 mg azo dye free tablet/mini tablet suspension/solid mini tablet/dye containing tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension, Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg roxadustat pediatric azo dye-free tablet or dye free mini tablet suspension or dye free solid mini tablet or dye containing tablet as per the dosing sequence.

Arm title	Treatment Sequence 4 (DCBA)

Arm description:

Participants received single dose of 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 3 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	Experimental
Investigational medicinal product name	Roxadustat 100 mg azo dye free tablet/mini tablet suspension/solid mini tablet/dye containing tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension, Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg roxadustat pediatric azo dye-free tablet or dye free mini tablet suspension or dye free solid mini tablet or dye containing tablet as per the dosing sequence.

Number of subjects in period 5	Treatment Sequence 1 (ABCD)	Treatment Sequence 2 (BDAC)	Treatment Sequence 3 (CADB)
Started	6	6	6
Completed	6	5	6
Not completed	0	1	0
Withdrawal by subject	-	1	-

Number of subjects in period 5	Treatment Sequence 4 (DCBA)
Started	5
Completed	5
Not completed	0
Withdrawal by subject	-

Period 6

Period 6 title	Washout Period 3 (7 days)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	Treatment Sequence 1 (ABCD)

Arm description:

Participants received single dose of 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 3 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Treatment Sequence 2 (BDAC)

Arm description:

Particpants received 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 1 followed by single dose of 100 mg of roxadustat azo dye-containing tablet (D), orally on day 1 in period 2 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Treatment Sequence 3 (CADB)

Arm description:

Participants received single dose of 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 1 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 2 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Treatment Sequence 4 (DCBA)

Arm description:

Participants received single dose of 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 3 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 6	Treatment Sequence 1 (ABCD)	Treatment Sequence 2 (BDAC)	Treatment Sequence 3 (CADB)
Started	6	5	6
Completed	6	5	6

Number of subjects in period 6	Treatment Sequence 4 (DCBA)

Started	5
Completed	5

Period 7

Period 7 title	Treatment Period 4 (6 days)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Treatment Sequence 1 (ABCD)

Arm description:

Participants received single dose of 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 3 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	Experimental
Investigational medicinal product name	Roxadustat 100 mg azo dye free tablet/mini tablet suspension/solid mini tablet/dye containing tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension, Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg roxadustat pediatric azo dye-free tablet or dye free mini tablet suspension or dye free solid mini tablet or dye containing tablet as per the dosing sequence.

Arm title	Treatment Sequence 2 (BDAC)

Arm description:

Particpants received 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 1 followed by single dose of 100 mg of roxadustat azo dye-containing tablet (D), orally on day 1 in period 2 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	Experimental
Investigational medicinal product name	Roxadustat 100 mg azo dye free tablet/mini tablet suspension/solid mini tablet/dye containing tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension, Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg roxadustat pediatric azo dye-free tablet or dye free mini tablet suspension or dye free solid mini tablet or dye containing tablet as per the dosing sequence.

Arm title	Treatment Sequence 3 (CADB)

Arm description:

Participants received single dose of 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 1 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 2 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	Experimental
Investigational medicinal product name	Roxadustat 100 mg azo dye free tablet/mini tablet suspension/solid mini tablet/dye containing tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension, Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg roxadustat pediatric azo dye-free tablet or dye free mini tablet suspension or dye free solid mini tablet or dye containing tablet as per the dosing sequence.

Arm title	Treatment Sequence 4 (DCBA)

Arm description:

Participants received single dose of 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 3 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Arm type	Experimental
Investigational medicinal product name	Roxadustat 100 mg azo dye free tablet/mini tablet suspension/solid mini tablet/dye containing tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension, Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 100 mg roxadustat pediatric azo dye-free tablet or dye free mini tablet suspension or dye free solid mini tablet or dye containing tablet as per the dosing sequence.

Number of subjects in period 7	Treatment Sequence 1 (ABCD)	Treatment Sequence 2 (BDAC)	Treatment Sequence 3 (CADB)
Started	6	5	6
Completed	6	5	6

Number of subjects in period 7	Treatment Sequence 4 (DCBA)
Started	5
Completed	5

Baseline characteristics

Reporting groups	
Reporting group title	Treatment Sequence 1 (ABCD)
Reporting group description:	
Participants received single dose of 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 3 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.	
Reporting group title	Treatment Sequence 2 (BDAC)
Reporting group description:	
Particpants received 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 1 followed by single dose of 100 mg of roxadustat azo dye-containing tablet (D), orally on day 1 in period 2 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.	
Reporting group title	Treatment Sequence 3 (CADB)
Reporting group description:	
Participants received 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 1 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 2 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.	
Reporting group title	Treatment Sequence 4 (DCBA)
Reporting group description:	
Participants received single dose of 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 3 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.	

Reporting group values	Treatment Sequence 1 (ABCD)	Treatment Sequence 2 (BDAC)	Treatment Sequence 3 (CADB)
Number of subjects	6	6	6
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	31.8	31.8	30.7
standard deviation	± 9.8	± 6.3	± 7.8
Gender categorical Units: Subjects			
M	2	1	4
F	4	5	2
Analysis Race Units: Subjects			
White	6	6	5
Asian	0	0	1
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	1
Not Hispanic or Latino	6	6	5

Reporting group values	Treatment Sequence 4 (DCBA)	Total	
Number of subjects	6	24	
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	30.2		
standard deviation	± 6.0	-	
Gender categorical Units: Subjects			
M	1	8	
F	5	16	
Analysis Race Units: Subjects			
White	6	23	
Asian	0	1	
Ethnicity Units: Subjects			
Hispanic or Latino	0	1	
Not Hispanic or Latino	6	23	

End points

End points reporting groups

Reporting group title	Treatment Sequence 1 (ABCD)

Reporting group description:

Participants received single dose of 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 3 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 2 (BDAC)

Reporting group description:

Particpants received 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 1 followed by single dose of 100 mg of roxadustat azo dye-containing tablet (D), orally on day 1 in period 2 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 3 (CADB)

Reporting group description:

Participants received 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 1 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 2 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 4 (DCBA)

Reporting group description:

Participants received single dose of 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 3 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 1 (ABCD)

Reporting group description:

Participants received single dose of 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 3 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 2 (BDAC)

Reporting group description:

Particpants received 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 1 followed by single dose of 100 mg of roxadustat azo dye-containing tablet (D), orally on day 1 in period 2 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 3 (CADB)

Reporting group description:

Participants received single dose of 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 1 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 2 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 4 (DCBA)

Reporting group description:

Participants received single dose of 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 3 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 1 (ABCD)

Reporting group description:

Participants received single dose of 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 3 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 2 (BDAC)

Reporting group description:

Particpants received 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 1 followed by single dose of 100 mg of roxadustat azo dye-containing tablet (D), orally on day 1 in period 2 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 3 (CADB)

Reporting group description:

Participants received single dose of 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 1 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 2 followed by single dose of 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 4 (DCBA)

Reporting group description:

Participants received single dose of 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 3 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 1 (ABCD)

Reporting group description:

Participants received single dose of 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 3 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 2 (BDAC)

Reporting group description:

Particpants received 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 1 followed by single dose of 100 mg of roxadustat azo dye-containing tablet (D), orally on day 1 in period 2 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 3 (CADB)

Reporting group description:

Participants received single dose of 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 1 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 2 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 4 (CADB)

Reporting group description:

Participants received single dose of 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 3 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 1 (ABCD)

Reporting group description:

Participants received single dose of 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on

day 1 in period 3 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 2 (BDAC)

Reporting group description:

Particpants received 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 1 followed by single dose of 100 mg of roxadustat azo dye-containing tablet (D), orally on day 1 in period 2 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 3 (CADB)

Reporting group description:

Participants received single dose of 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 1 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 2 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 4 (DCBA)

Reporting group description:

Participants received single dose of 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 3 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 1 (ABCD)

Reporting group description:

Participants received single dose of 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 3 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 2 (BDAC)

Reporting group description:

Particpants received 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 1 followed by single dose of 100 mg of roxadustat azo dye-containing tablet (D), orally on day 1 in period 2 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 3 (CADB)

Reporting group description:

Participants received single dose of 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 1 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 2 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 4 (DCBA)

Reporting group description:

Participants received single dose of 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 3 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 1 (ABCD)

Reporting group description:

Participants received single dose of 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 3 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 2 (BDAC)

Reporting group description:

Particpants received 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day

1 in period 1 followed by single dose of 100 mg of roxadustat azo dye-containing tablet (D), orally on day 1 in period 2 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 3 (CADB)

Reporting group description:

Participants received single dose of 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 1 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 2 followed by 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 3 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Reporting group title	Treatment Sequence 4 (DCBA)

Reporting group description:

Participants received single dose of 100 mg roxadustat azo dye-containing tablet (D), orally on day 1 in period 1 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet solid (C), orally on day 1 in period 2 followed by 100 mg roxadustat pediatric azo dye-free mini-tablet suspension (B), orally on day 1 in period 3 followed by 100 mg of roxadustat pediatric azo dye-free tablet (A), orally on day 1 in period 4. Each period was of 6 days. A washout period of 7 days was included between each period.

Subject analysis set title	Roxadustat azo dye-free tablet 100 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 100 mg roxadustat pediatric azo dye-free tablet, orally on day 1 as per the dosing sequence in each period.

Subject analysis set title	Roxadustat azo dye-free mini tablet suspension 100 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 100 mg roxadustat pediatric azo dye-free mini-tablet suspension, orally on day 1 as per the dosing sequence in each period.

Subject analysis set title	Roxadustat azo dye-free mini tablet 100 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 100 mg roxadustat pediatric azo dye-free solid mini-tablet, orally on day 1 as per the dosing sequence in each period.

Subject analysis set title	Roxadustat azo dye-containing tablet 100 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 100 mg roxadustat azo dye-containing tablet, orally on day 1 as per the dosing sequence in each period.

Primary: Area Under the Curve From Time of Dosing Extrapolated to Time Infinity (AUCinf) for Roxadustat

End point title	Area Under the Curve From Time of Dosing Extrapolated to Time Infinity (AUCinf) for Roxadustat

End point description:

AUCinf was defined as area under the plasma concentration versus time curve from time of dosing (pre-dose) to extrapolated infinite time (0-inf). The analysis population was pharamcokinetic analysis set (PKAS) which included all randomized participants who received at least 1 dose of study drug and for which concentration data were available to facilitate derivation of at least 1 primary pharmacokinetic parameter and who had available data.

End point type	Primary

End point timeframe:

Predose (0 hour), 0.25, 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16, 24, 36, 48 and 72 hours postdose on day 1

End point values	Roxadustat azo dye-free tablet 100 mg	Roxadustat azo dye-free mini tablet suspension 100 mg	Roxadustat azo dye-free mini tablet 100 mg	Roxadustat azo dye-containing tablet 100 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	23	22	23
Units: hour*nanogram per milliliter (h*ng/mL)				
arithmetic mean (standard deviation)	53200 (± 13200)	56400 (± 13600)	53100 (± 12100)	54500 (± 11400)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Assessment based on an analysis of variance performed on natural log-transformed parameter with sequence, period and formulation as fixed effects and participants as a random effect. Ratios and confidence limits are transformed back to raw scale and values are expressed as percentages. The actual number of participants analyzed is 23, (and not 45; this is a system limitation).

Comparison groups	Roxadustat azo dye-free tablet 100 mg v Roxadustat azo dye-containing tablet 100 mg
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Geometric LS Mean Ratio
Point estimate	98.07
Confidence interval	
level	90 %
sides	2-sided
lower limit	93.81
upper limit	102.52

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Assessment based on an analysis of variance performed on natural log-transformed parameter with sequence, period and formulation as fixed effects and participants as a random effect. Ratios and confidence limits are transformed back to raw scale and values are expressed as percentages. The actual number of participants analyzed is 23, (and not 46; this is a system limitation).

Comparison groups	Roxadustat azo dye-free mini tablet suspension 100 mg v Roxadustat azo dye-containing tablet 100 mg
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Geometric LS Mean Ratio
Point estimate	103.13
Confidence interval	
level	90 %
sides	2-sided
lower limit	98.73
upper limit	107.73

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Assessment based on an analysis of variance performed on natural log-transformed parameter with sequence, period and formulation as fixed effects and participants as a random effect. Ratios and confidence limits are transformed back to raw scale and values are expressed as percentages. The actual number of participants analyzed is 23, (and not 45; this is a system limitation).

Comparison groups	Roxadustat azo dye-free mini tablet 100 mg v Roxadustat azo dye-containing tablet 100 mg
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Geometric LS Mean Ratio
Point estimate	98.08
Confidence interval	
level	90 %
sides	2-sided
lower limit	93.82
upper limit	102.53

Primary: Area Under the Concentration-Time Curve From the Time of Dosing to Last Measurable Concentration (AUClast) for Roxadustat

End point title	Area Under the Concentration-Time Curve From the Time of Dosing to Last Measurable Concentration (AUClast) for Roxadustat

End point description:

AUClast was defined as area under the plasma concentration time-curve from time of dosing to the last measured concentration. The analysis population consisted of PKAS and who had available data.

End point type	Primary

End point timeframe:

Predose (0 hour), 0.25, 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16, 24, 36, 48 and 72 hours postdose on day 1

End point values	Roxadustat azo dye-free tablet 100 mg	Roxadustat azo dye-free mini tablet suspension 100 mg	Roxadustat azo dye-free mini tablet 100 mg	Roxadustat azo dye-containing tablet 100 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	23	22	23
Units: h*ng/mL				
arithmetic mean (standard deviation)	53000 (± 13100)	56100 (± 13400)	52800 (± 11900)	54200 (± 11300)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Assessment based on an analysis of variance performed on natural log-transformed parameter with sequence, period and formulation as fixed effects and participants as a random effect. Ratios and confidence limits are transformed back to raw scale and values are expressed as percentages. The actual number of participants analyzed is 23, (and not 45; this is a system limitation).

Comparison groups	Roxadustat azo dye-free tablet 100 mg v Roxadustat azo dye-containing tablet 100 mg
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Geometric LS Mean Ratio
Point estimate	98.15
Confidence interval	
level	90 %
sides	2-sided
lower limit	93.85
upper limit	102.63

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Assessment based on an analysis of variance performed on natural log-transformed parameter with sequence, period and formulation as fixed effects and participants as a random effect. Ratios and confidence limits are transformed back to raw scale and values are expressed as percentages. The actual number of participants analyzed is 23, (and not 46; this is a system limitation).

Comparison groups	Roxadustat azo dye-free mini tablet suspension 100 mg v Roxadustat azo dye-containing tablet 100 mg
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Geometric LS Mean Ratio
Point estimate	103.22
Confidence interval	
level	90 %
sides	2-sided
lower limit	98.78
upper limit	107.85

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Assessment based on an analysis of variance performed on natural log-transformed parameter with sequence, period and formulation as fixed effects and participants as a random effect. Ratios and confidence limits are transformed back to raw scale and values are expressed as percentages. The actual number of participants analyzed is 23, (and not 45; this is a system limitation).

Comparison groups	Roxadustat azo dye-free mini tablet 100 mg v Roxadustat azo dye-containing tablet 100 mg

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Geometric LS Mean Ratio
Point estimate	98.08
Confidence interval	
level	90 %
sides	2-sided
lower limit	93.79
upper limit	102.57

Primary: Pharmacokinetics (PK) of Maximum Observed Concentration of Roxadustat

End point title	Pharmacokinetics (PK) of Maximum Observed Concentration of Roxadustat

End point description:

Maximum observed concentration (Cmax) was reported. The analysis population consisted of PKAS and with available data.

End point type	Primary

End point timeframe:

Predose (0 hour), 0.25, 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16, 24, 36, 48 and 72 hours postdose on day 1

End point values	Roxadustat azo dye-free tablet 100 mg	Roxadustat azo dye-free mini tablet suspension 100 mg	Roxadustat azo dye-free mini tablet 100 mg	Roxadustat azo dye-containing tablet 100 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	23	22	24
Units: nanogram per milliliter				
arithmetic mean (standard deviation)	8220 (± 1790)	8230 (± 1840)	7810 (± 1690)	8270 (± 1770)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Assessment based on an analysis of variance performed on natural log-transformed parameter with sequence, period and formulation as fixed effects and participants as a random effect. Ratios and confidence limits are transformed back to raw scale and values are expressed as percentages. The actual number of participants analyzed is 24, (and not 46; this is a system limitation).

Comparison groups	Roxadustat azo dye-free tablet 100 mg v Roxadustat azo dye-containing tablet 100 mg

Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Geometric LS Mean Ratio
Point estimate	99.62
Confidence interval	
level	90 %
sides	2-sided
lower limit	91.69
upper limit	108.24

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Assessment based on an analysis of variance performed on natural log-transformed parameter with sequence, period and formulation as fixed effects and participants as a random effect. Ratios and confidence limits are transformed back to raw scale and values are expressed as percentages. The actual number of participants analyzed is 24, (and not 47; this is a system limitation).

Comparison groups	Roxadustat azo dye-free mini tablet suspension 100 mg v Roxadustat azo dye-containing tablet 100 mg
Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Geometric LS Mean Ratio
Point estimate	98.84
Confidence interval	
level	90 %
sides	2-sided
lower limit	91.09
upper limit	107.25

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Assessment based on an analysis of variance performed on natural log-transformed parameter with sequence, period and formulation as fixed effects and participants as a random effect. Ratios and confidence limits are transformed back to raw scale and values are expressed as percentages. The actual number of participants analyzed is 24, (and not 46; this is a system limitation).

Comparison groups	Roxadustat azo dye-free mini tablet 100 mg v Roxadustat azo dye-containing tablet 100 mg
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Geometric LS Mean Ratio
Point estimate	94.45
Confidence interval	
level	90 %
sides	2-sided
lower limit	86.93
upper limit	102.62

Secondary: Percentage of the Area Under the Concentration-Time Curve From the Time of Dosing to Time infinity due to Extrapolation From the Last Measurable Concentration to Time Infinity (AUCinf[%extrap]) for Roxadustat

End point title	Percentage of the Area Under the Concentration-Time Curve From the Time of Dosing to Time infinity due to Extrapolation From the Last Measurable Concentration to Time Infinity (AUCinf[%extrap]) for Roxadustat

End point description:

AUC%extrap was defined as the percentage of AUC [0-∞] obtained by forward extrapolation. It is calculated as (AUC [0-∞] minus AUClast)*100/ AUC [0-∞], where AUC [0-∞] = area under the plasma concentration versus time curve from time zero (pre-dose) to extrapolated infinite time (0-∞) and AUClast is area under the plasma concentration time-curve from zero (pre-dose) to the last measured concentration. The analysis population consisted of PKAS and with available data.

End point type	Secondary

End point timeframe:

Predose (0 hour), 0.25, 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16, 24, 36, 48 and 72 hours postdose on day 1

End point values	Roxadustat azo dye-free tablet 100 mg	Roxadustat azo dye-free mini tablet suspension 100 mg	Roxadustat azo dye-free mini tablet 100 mg	Roxadustat azo dye-containing tablet 100 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	23	22	23
Units: % extrap				
arithmetic mean (standard deviation)	0.400 (± 0.432)	0.439 (± 0.526)	0.464 (± 0.590)	0.520 (± 0.605)

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Total Systemic Clearance of Roxadustat After Extravascular Dosing (CL/F)

End point title	Apparent Total Systemic Clearance of Roxadustat After Extravascular Dosing (CL/F)

End point description:

Clearance of a drug is a measure of the rate at which a drug is metabolized or eliminated by normal biological processes. Clearance obtained after oral dose (apparent oral clearance) is influenced by the fraction of the dose absorbed. The analysis population consisted of PKAS and with available data.

End point type	Secondary

End point timeframe:

Predose (0 hour), 0.25, 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16, 24, 36, 48 and 72 hours postdose on day 1

End point values	Roxadustat azo dye-free tablet 100 mg	Roxadustat azo dye-free mini tablet suspension 100 mg	Roxadustat azo dye-free mini tablet 100 mg	Roxadustat azo dye-containing tablet 100 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	23	22	23
Units: Liter per hour				
arithmetic mean (standard deviation)	2.00 (± 0.519)	1.89 (± 0.530)	2.00 (± 0.553)	1.93 (± 0.476)

Statistical analyses

No statistical analyses for this end point

Secondary: Terminal Elimination Half-life (t1/2) of Roxadustat

End point title	Terminal Elimination Half-life (t1/2) of Roxadustat

End point description:

Plasma decay half-life is the time measured for the plasma concentration to decrease by one half. The analysis population consisted of PKAS and with available data.

End point type	Secondary

End point timeframe:

Predose (0 hour), 0.25, 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16, 24, 36, 48 and 72 hours postdose on day 1

End point values	Roxadustat azo dye-free tablet 100 mg	Roxadustat azo dye-free mini tablet suspension 100 mg	Roxadustat azo dye-free mini tablet 100 mg	Roxadustat azo dye-containing tablet 100 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	23	22	23
Units: hour				
arithmetic mean (standard deviation)	9.62 (± 1.80)	9.88 (± 2.09)	9.43 (± 2.58)	9.81 (± 1.62)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Reach Maximum Concentration (tmax) of Roxadustat

End point title	Time to Reach Maximum Concentration (tmax) of Roxadustat

End point description:

Time to reach maximum concentration of roxadustat following drug administration (tmax) was reported. The analysis population consisted of PKAS and with available data.

End point type	Secondary

End point timeframe:

Predose (0 hour), 0.25, 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16, 24, 36, 48 and 72 hours postdose on day 1

End point values	Roxadustat azo dye-free tablet 100 mg	Roxadustat azo dye-free mini tablet suspension 100 mg	Roxadustat azo dye-free mini tablet 100 mg	Roxadustat azo dye-containing tablet 100 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	23	22	24
Units: hour				
median (full range (min-max))	2.00 (0.500 to 4.00)	2.00 (1.00 to 4.00)	2.00 (1.00 to 5.00)	2.25 (0.500 to 5.07)

Statistical analyses

No statistical analyses for this end point

Secondary: Time Prior to the Time Corresponding to the First Measurable (nonzero) Concentration (tlag) of Roxadustat

End point title	Time Prior to the Time Corresponding to the First Measurable (nonzero) Concentration (tlag) of Roxadustat

End point description:

Tlag was defined as the time prior to the time corresponding to the first measurable concentration. The analysis population consisted of PKAS and with available data.

End point type	Secondary

End point timeframe:

Predose (0 hour), 0.25, 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16, 24, 36, 48 and 72 hours postdose on day 1

End point values	Roxadustat azo dye-free tablet 100 mg	Roxadustat azo dye-free mini tablet suspension 100 mg	Roxadustat azo dye-free mini tablet 100 mg	Roxadustat azo dye-containing tablet 100 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	23	22	24
Units: hour				
median (full range (min-max))	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Volume of Distribution During the Terminal Elimination Phase After Extravascular Dosing (Vz/F) of Roxadustat

End point title	Apparent Volume of Distribution During the Terminal Elimination Phase After Extravascular Dosing (Vz/F) of Roxadustat

End point description:

Volume of distribution is defined as the theoretical volume in which the total amount of drug would need to be uniformly distributed to produce the desired plasma concentration of a drug. Apparent volume of distribution after oral dose (Vz/F) is influenced by the fraction absorbed. The analysis population consisted of PKAS and with available data.

End point type	Secondary

End point timeframe:

Predose (0 hour), 0.25, 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16, 24, 36, 48 and 72 hours postdose on day 1

End point values	Roxadustat azo dye-free tablet 100 mg	Roxadustat azo dye-free mini tablet suspension 100 mg	Roxadustat azo dye-free mini tablet 100 mg	Roxadustat azo dye-containing tablet 100 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	23	22	23
Units: Liter				
arithmetic mean (standard deviation)	27.4 (± 7.79)	26.9 (± 9.07)	26.5 (± 7.05)	26.9 (± 6.14)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment-Emergent Adverse Event (TEAEs)

End point title	Number of Participants With Treatment-Emergent Adverse Event (TEAEs)

End point description:

An AE was defined as any untoward medical occurrence in a participant who was given the study drug or who had undergone study procedures and did not necessarily have a causal relationship with this treatment. An AE could therefore be any unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. A treatment-emergent adverse event was defined as an adverse event with onset at any time from dosing until the last scheduled procedure. Safety analysis set included all randomized participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

From first dose of study drug up to end of study visit (up to 54 days)

End point values	Roxadustat azo dye-free tablet 100 mg	Roxadustat azo dye-free mini tablet suspension 100 mg	Roxadustat azo dye-free mini tablet 100 mg	Roxadustat azo dye-containing tablet 100 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	23	22	24
Units: participants	5	4	6	3

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From first dose of study drug up to end of study visit (up to 54 days)	
Adverse event reporting additional description:	
Safety analysis set included all randomized participants who received at least 1 dose of study drug.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups	
Reporting group title	Roxadustat azo dye-free tablet 100 mg
Reporting group description:	
Participants received 100 mg roxadustat pediatric azo dye-free tablet, orally on day 1 in each period.	
Reporting group title	Roxadustat azo dye-free mini tablet suspension 100 mg
Reporting group description:	
Participants received 100 mg roxadustat pediatric azo dye-free mini-tablet suspension, orally on day 1 in each period.	
Reporting group title	Roxadustat azo dye-free mini tablet 100 mg
Reporting group description:	
Participants received 100 mg roxadustat pediatric azo dye-free solid mini-tablet, orally on day 1 in each period.	
Reporting group title	Roxadustat azo dye-containing tablet 100 mg
Reporting group description:	
Participants received 100 mg roxadustat azo dye-containing tablet, orally on day 1 in each period.	

Serious adverse events	Roxadustat azo dye-free tablet 100 mg	Roxadustat azo dye-free mini tablet suspension 100 mg	Roxadustat azo dye-free mini tablet 100 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 22 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	Roxadustat azo dye-containing tablet 100 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 24 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Roxadustat azo dye-free tablet 100 mg	Roxadustat azo dye-free mini tablet suspension 100 mg	Roxadustat azo dye-free mini tablet 100 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 22 (13.64%)	4 / 23 (17.39%)	2 / 22 (9.09%)
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 22 (4.55%)	3 / 23 (13.04%)	1 / 22 (4.55%)
occurrences (all)	1	4	1
General disorders and administration site conditions			
Catheter site related reaction			
subjects affected / exposed	0 / 22 (0.00%)	2 / 23 (8.70%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 22 (0.00%)	2 / 23 (8.70%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 22 (9.09%)	1 / 23 (4.35%)	1 / 22 (4.55%)
occurrences (all)	3	1	1

Non-serious adverse events	Roxadustat azo dye-containing tablet 100 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 24 (12.50%)		
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
General disorders and administration site conditions			

Catheter site related reaction subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0		
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all)	2 / 24 (8.33%) 2		
Infections and infestations Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 June 2019	The changes included: 1.Addition of text to clarify that informed consent was to be obtained and signed by the participant prior to any study-related procedures at screening and that the participant must have met all the inclusion and none of the exclusion criteria on day -1. 2.Update of the alcohol exclusionary alcohol consumption limit for males and females in the exclusion criteria from a higher allowed weekly limit to a lower allowed daily limit. 3.Addition of exclusion criterion to exclude participants with abnormal renal function, indicated by creatinine above the upper limit of normal or chronic kidney disease (CKD) epidemiology collaboration based on the estimated glomerular filtration rate of < 90 milliliter/minute (mL/min) on day -1. 4. Addition of pregnancy to the reasons why a participant must have discontinued from study treatment. 5. Update to text to state that the premature termination of the study for reasonable cause was not optional. Addition of reasons that was to result in premature discontinuation of the study and of text to state that the whole study may have been terminated or suspended upon the request of regulatory authorities. In addition, text was added to state that regulatory authorities and the independent ethics committee (IEC) was to be informed about the discontinuation of the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported