Clinical trial results:
Influence of UDCA on fecal bile salt composition of IBD patients: pilot study

Summary

EudraCT number	2014-003141-10
Trial protocol	BE
Global end of trial date	10 January 2019

Results information

Result version number	v1 (current)
This version publication date	04 December 2021
First version publication date	04 December 2021
Summary attachment (see zip file)	Summary (2014-003141-10.docx)

Trial information

Trial identification

Sponsor protocol code	AGO/2014/004

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Ghent University Hospital
Sponsor organisation address	Corneel Heymanslaan 10, Ghent, Belgium, 9000
Public contact	Hiruz CTU, Ghent University Hospital, +32 93320500, hiruz.ctu@uzgent.be
Scientific contact	Hiruz CTU, Ghent University Hospital, +32 93320500, hiruz.ctu@uzgent.be

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	07 September 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 September 2016
Global end of trial reached?	Yes
Global end of trial date	10 January 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To research the effects of UDCA administration on the fecal metabolites (especially bile salts) and fecal microbiota of IBD patients and healthy volunteers.

Protection of trial subjects:

Ethics review and approval, informed consent, supportive care and routine monitoring.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 November 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 54
Worldwide total number of subjects	54
EEA total number of subjects	54

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)	52
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

54 patients were screened from 05-06-2015 till 07-09-2016. 54 patients were enrolled. Patients that completed the study could not be determined as 32 CRFs were not completed/available. End of trial notification was dated 07-09-2016 (last patient last visit) and submitted to EC and CA 10-01-2019.

Pre-assignment

Screening details:

Control group: age between 18-65 yrs, abscence of important gastrointestinal co-morbidity
IBD group: Crohn's disease or Colitis ulcerosa, active disease at inclusion (CDAI ≥ 150 or UCDAI ≥ 3)
IBD remission group: Crohn's disease or Colitis ulcerosa, Clinical remission (CDAI < 150 or UCDAI ≤ 2)
PSC group: known PSC, Chronic treatment with UDCA

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

N/A

Arms

Are arms mutually exclusive?	Yes
Arm title	Treatment arm

Arm description:

Two groups of patients were included. All patients received ursodeoxycholic acid:
active IBD group (20 individuals), IBD remission group (1 individual)

Arm type	Experimental
Investigational medicinal product name	Ursodeoxycholic acid
Investigational medicinal product code	
Other name	UrsoFalk
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Per day, 250 mg milligram(s)

Arm title	No treatment arm

Arm description:

No treatment arm contains the healthy volunteer group (25 individuals) and primary sclerosing cholangitis group (0 individuals).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Unknown

Arm description:

ICF IBD signed but no CRF completed and thus impossible to determine in which group the subjects were enrolled.

Arm type	unkown

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Treatment arm	No treatment arm	Unknown
Started	21	25	8
Completed	0	0	0
Not completed	21	25	8
impossible to determine: 32 CRFs were incomplete	21	25	8

Baseline characteristics

Reporting groups	
Reporting group title	Treatment arm
Reporting group description:	
Two groups of patients were included. All patients received ursodeoxycholic acid: active IBD group (20 individuals), IBD remission group (1 individual)	
Reporting group title	No treatment arm
Reporting group description:	
No treatment arm contains the healthy volunteer group (25 individuals) and primary sclerosing cholangitis group (0 individuals).	
Reporting group title	Unknown
Reporting group description:	
ICF IBD signed but no CRF completed and thus impossible to determine in which group the subjects were enrolled.	

Reporting group values	Treatment arm	No treatment arm	Unknown
Number of subjects	21	25	8
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	19	25	8
From 65-84 years	2	0	0
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	8	12	4
Male	13	13	4

Reporting group values	Total		
Number of subjects	54		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	52		
From 65-84 years	2		
85 years and over	0		

Gender categorical Units: Subjects			
Female	24		
Male	30		

End points

End points reporting groups

Reporting group title	Treatment arm
Reporting group description:	
Two groups of patients were included. All patients received ursodeoxycholic acid: active IBD group (20 individuals), IBD remission group (1 individual)	
Reporting group title	No treatment arm
Reporting group description:	
No treatment arm contains the healthy volunteer group (25 individuals) and primary sclerosing cholangitis group (0 individuals).	
Reporting group title	Unknown
Reporting group description:	
ICF IBD signed but no CRF completed and thus impossible to determine in which group the subjects were enrolled.	

Primary: Change in fecal metabolite composition (especially bile salts)

End point title	Change in fecal metabolite composition (especially bile salts)[1]
End point description:	
End point type	Primary
End point timeframe:	
Until 4 weeks after start of study.	

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 statistical analysis available

End point values	Treatment arm	No treatment arm	Unknown	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[2]	0[3]	0[4]	
Units: metabolite composition				
number (not applicable)				

Notes:

[2] - Impossible to determine as 32 CRFs were not completed/available.

[3] - Impossible to determine as 32 CRFs were not completed/available.

[4] - Impossible to determine as 32 CRFs were not completed/available.

Statistical analyses

No statistical analyses for this end point

Primary: Change in fecal microbiota composition

End point title	Change in fecal microbiota composition[5]
End point description:	
End point type	Primary
End point timeframe:	
Until 4 weeks after start of study.	

Notes:

[5] - 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 statistical analysis available

End point values	Treatment arm	No treatment arm	Unknown	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[6]	0[7]	0[8]	
Units: microbiota composition				
number (not applicable)				

Notes:

[6] - Impossible to determine as 32 CRFs were not completed/available.

[7] - Impossible to determine as 32 CRFs were not completed/available.

[8] - Impossible to determine as 32 CRFs were not completed/available.

Statistical analyses

No statistical analyses for this end point

Secondary: Tolerability of UDCA administration (adverse effects)

End point title	Tolerability of UDCA administration (adverse effects)

End point description:

End point type	Secondary

End point timeframe:

Until 4 weeks after start of study.

End point values	Treatment arm	No treatment arm	Unknown	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[9]	0[10]	0[11]	
Units: adverse effects				

Notes:

[9] - Impossible to determine as 32 CRFs were not completed/available.

[10] - Impossible to determine as 32 CRFs were not completed/available.

[11] - Impossible to determine as 32 CRFs were not completed/available.

Statistical analyses

No statistical analyses for this end point

Secondary: Change in CDAI/UCDAI score, calprotectin levels

End point title	Change in CDAI/UCDAI score, calprotectin levels

End point description:

End point type	Secondary

End point timeframe:

Until 4 weeks after start of study.

End point values	Treatment arm	No treatment arm	Unknown	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[12]	0[13]	0[14]	
Units: calprotectin levels				
number (not applicable)				

Notes:

[12] - Impossible to determine as 32 CRFs were not completed/available.

[13] - Impossible to determine as 32 CRFs were not completed/available.

[14] - Impossible to determine as 32 CRFs were not completed/available.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Overall Study

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24

Reporting groups

Reporting group title	Treatment arm

Reporting group description:

Two groups of patients were included. All patients received ursodeoxycholic acid:
active IBD group (20 individuals), IBD remission group (1 individual)

Reporting group title	No treatment arm

Reporting group description:

No treatment arm contains the healthy volunteer group (26 individuals) and primary sclerosing cholangitis group (0 individuals).

Reporting group title	Unknown

Reporting group description:

ICF IBD signed but no CRF completed and thus impossible to determine in which group the subjects were enrolled.

Serious adverse events	Treatment arm	No treatment arm	Unknown
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 21 (0.00%)	0 / 26 (0.00%)	0 / 8 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

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

Non-serious adverse events	Treatment arm	No treatment arm	Unknown
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 21 (0.00%)	0 / 26 (0.00%)	0 / 8 (0.00%)

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No non-serious adverse events were recorded for the participating patients

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 December 2014	Amendment to information of the CT application form, the protocol and the ICF form have been made due to a change in the quality of IMP and conduct or management of the trial. - Commercial investigational product was changed from Ursochol (150 mg tablets) to UrsoFalk (250 mg tablets). Active component remained the same. - An extra group of patients was added: a PSC group (=Patients with known primary sclerosing cholangitis).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

32 CRFs were not completed/available. No articles were published as no sufficient data was available.

Notes: