



Clinical trial results: ChAracterizing the Remission status in patients with Ulcerative Colitis treated by 5-ASA

Summary

EudraCT number	2022-001683-10
Trial protocol	BE
Global end of trial date	01 February 2024

Results information

Result version number	v1 (current)
This version publication date	23 July 2026
First version publication date	23 July 2026

Trial information

Trial identification

Sponsor protocol code	BIRD2022001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05992142
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	BIRD vzw (Belgian IBD Research & Development)
Sponsor organisation address	Leuvensesteenweg 643, Zaventem , Belgium, 1930
Public contact	Ingrid Arijs, BIRD vzw, +32 0499 31 70 05, ingrid.arijs@birdgroup.be
Scientific contact	Ingrid Arijs, BIRD vzw, +32 0499 31 70 05, ingrid.arijs@birdgroup.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	01 February 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 February 2024
Global end of trial reached?	Yes
Global end of trial date	01 February 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this trial is to describe the percentage of the different levels of remission (clinical, endoscopic, histological, biological), in UC patients, treated by 5-ASA for at least 6 months, free of concomitant UC medications for at least 3 months and presenting for a routine follow-up visit.

Protection of trial subjects:

This clinical trial was conducted in compliance with the most recent version of the principles of the Declaration of Helsinki, the principles of Good Clinical Practice, and in accordance with all applicable regulatory requirements. The study was conducted on the basis of prior informed consent by the subjects to participate in the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 January 2023
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	Belgium: 200
Worldwide total number of subjects	200
EEA total number of subjects	200

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)	153
From 65 to 84 years	45

85 years and over	2
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Subject disposition

Recruitment

Recruitment details:

Between January 2023 and February 2024 a total of 205 patients were screened and 200 patients were enrolled (2 patients were excluded for analysis).

First Patient In (FPI) was on 17Jan2023.

Last Patient In (LPI) was on 23Jan2024.

Last Patient Out (LPO) was on 1Feb2024.

Pre-assignment

Screening details:

UC patients (≥ 18 years) to whom 5-ASA has been prescribed for at least 6 months with dose stable for at least 2 weeks prior to inclusion. Patients were free of concomitant UC medication (corticosteroids, immunomodulators, biologics, JAK inhibitors, S1PR modulators or IP) for at least 3 months. Patients were recruited during a routine visit.

Period 1

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

Arms

Arm title	Included patients for analysis
Arm description: -	
Arm type	5-ASA
Investigational medicinal product name	5-ASA
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Suppository, Rectal foam, Gastro-resistant granules, Rectal suspension, Gastro-resistant tablet, Granules
Routes of administration	Rectal use, Oral use

Dosage and administration details:

5-ASA : All possible dosages and forms of administration (oral and/or rectal) prescribed in routine practice according to locally approved SmPC's - the study does not interfere with the therapeutic decisions of the treating physician at any point.

Number of subjects in period 1 ^[1]	Included patients for analysis
Started	198
Completed	198

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: 200 patients were enrolled, but only 198 patients were analysed. Two patients were excluded from analysis due to protocol violations.

Baseline characteristics

Reporting groups

Reporting group title	Overall trial
Reporting group description: -	

Reporting group values	Overall trial	Total	
Number of subjects	198	198	
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)	151	151	
From 65-84 years	45	45	
85 years and over	2	2	
Age continuous			
Units: years			
median	50		
inter-quartile range (Q1-Q3)	38 to 63	-	
Gender categorical			
Units: Subjects			
Female	82	82	
Male	116	116	
Smoking status			
Units: Subjects			
Smoker (> 1 cigarette/day)	12	12	
Non-smoker	113	113	
Former smoker	73	73	
UC Montreal Classification			
Units: Subjects			
E1 (Ulcerative proctitis)	73	73	
E2 (left-sided UC)	87	87	
E3 (Extensive)	13	13	
Pancolitis	23	23	
Unknown	2	2	
Disease duration			
Units: years			
median	7		
inter-quartile range (Q1-Q3)	3 to 15	-	

End points

End points reporting groups

Reporting group title	Included patients for analysis
Reporting group description: -	

Primary: the percentage of Complete Clinical Remission (CCR)

End point title	the percentage of Complete Clinical Remission (CCR) ^[1]
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End point description:

Complete Clinical Remission is defined as PRO-2 = 0 and no bowel urgency (PRO-2 : Stool Frequency and Rectal Bleeding)

End point type	Primary
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End point timeframe:

Inclusion visit

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: Only descriptive statistics were performed for this primary endpoint.

End point values	Included patients for analysis			
Subject group type	Reporting group			
Number of subjects analysed	198			
Units: Percentage of subjects with CCR	37			

Statistical analyses

No statistical analyses for this end point

Primary: the percentage of Endoscopic Remission (ER)

End point title	the percentage of Endoscopic Remission (ER) ^[2]
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End point description:

Endoscopic remission is defined by an endoscopic MAYO subscore (MES) of 0 or 1 and by a Ulcerative Colitis Endoscopic Index of Severity (UCEIS) of 0 or 1

End point type	Primary
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End point timeframe:

Inclusion visit

Notes:

[2] - 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: Only descriptive statistics were performed for this primary endpoint.

End point values	Included patients for analysis			
Subject group type	Reporting group			
Number of subjects analysed	198			
Units: Percentage of subjects with ER	87			

Statistical analyses

No statistical analyses for this end point

Primary: the percentage of Complete Endoscopic Remission (CER)

End point title	the percentage of Complete Endoscopic Remission (CER) ^[3]
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End point description:

Complete endoscopic remission is defined as Mayo Endoscopic Subscore (MES) of 0 and by Ulcerative Colitis Endoscopic Index of Severity (UCEIS) of 0

End point type	Primary
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End point timeframe:

Inclusion visit

Notes:

[3] - 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: Only descriptive statistics were performed for this primary endpoint.

End point values	Included patients for analysis			
Subject group type	Reporting group			
Number of subjects analysed	198			
Units: Percentage of subjects with CER	70			

Statistical analyses

No statistical analyses for this end point

Primary: the percentage of Histological Remission (HR)

End point title	the percentage of Histological Remission (HR) ^[4]
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End point description:

Histological remission is defined by the absence of any acute inflammatory activity on the biopsies according to the Geboes score, including Geboes 0-1

End point type	Primary
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End point timeframe:

Inclusion visit

Notes:

[4] - 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: Only descriptive statistics were performed for this primary endpoint.

End point values	Included patients for analysis			
Subject group type	Reporting group			
Number of subjects analysed	196			
Units: Percentage of subjects with HR	80			

Statistical analyses

No statistical analyses for this end point

Primary: the percentage of Biological Remission (BR)

End point title	the percentage of Biological Remission (BR) ^[5]
End point description:	Biological Remission is defined by FCP < 150 µg/g (FCP : Fecal Calprotectin)
End point type	Primary
End point timeframe:	
Inclusion visit	

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: Only descriptive statistics were performed for this primary endpoint.

End point values	Included patients for analysis			
Subject group type	Reporting group			
Number of subjects analysed	194			
Units: Percentage of subjects with BR	78			

Statistical analyses

No statistical analyses for this end point

Primary: the percentage of Deep Remission (DR)

End point title	the percentage of Deep Remission (DR) ^[6]
End point description:	Deep Remission is defined as a combination of Complete Clinical Remission, Complete Endoscopic Remission and Histological Remission.
End point type	Primary
End point timeframe:	
Inclusion visit	

Notes:

[6] - 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: Only descriptive statistics were performed for this primary endpoint.

End point values	Included patients for analysis			
Subject group type	Reporting group			
Number of subjects analysed	197			
Units: Percentage of subjects with DR	24			

Statistical analyses

No statistical analyses for this end point

Secondary: the proportion of prescription of different current 5-ASA regimens (administration form)

End point title	the proportion of prescription of different current 5-ASA regimens (administration form)
End point description: to describe the prescription of different current 5-ASA regimens (administration form)	
End point type	Secondary
End point timeframe:	
Inclusion visit	

End point values	Included patients for analysis			
Subject group type	Reporting group			
Number of subjects analysed	198			
Units: subjects				
Oral	134			
Rectal	19			
Combined (oral + rectal)	45			

Statistical analyses

No statistical analyses for this end point

Secondary: the proportion of prescription of different current 5-ASA regimens (dose for oral monotherapy)

End point title	the proportion of prescription of different current 5-ASA regimens (dose for oral monotherapy)
End point description: to describe the prescription of different current 5-ASA regimens (dose for oral monotherapy only)	
End point type	Secondary
End point timeframe:	
Inclusion visit	

End point values	Included patients for analysis			
Subject group type	Reporting group			
Number of subjects analysed	134			
Units: subjects				
High dose (>3g/d)	23			
Normal dose (2-3g/d)	84			
Low dose (< 2g/d)	27			

Statistical analyses

No statistical analyses for this end point

Secondary: to describe adherence to 5-ASA treatment

End point title	to describe adherence to 5-ASA treatment
End point description:	
Adherence to 5-ASA was assessed using the MARS-5 questionnaire (higher score represents higher adherence)	
End point type	Secondary
End point timeframe:	
Inclusion visit	

End point values	Included patients for analysis			
Subject group type	Reporting group			
Number of subjects analysed	198			
Units: points				
median (inter-quartile range (Q1-Q3))	24 (23 to 25)			

Statistical analyses

No statistical analyses for this end point

Secondary: to describe Quality of Life (Symptoms)

End point title	to describe Quality of Life (Symptoms)
End point description:	
Quality of life was evaluated using the Short-Health-Scale questionnaire, based on four questions using a visual analogue scale (with maximum score 100). For the question related to 'symptoms' higher scores mean more severe symptoms.	
End point type	Secondary

End point timeframe:

Inclusion Visit

End point values	Included patients for analysis			
Subject group type	Reporting group			
Number of subjects analysed	198			
Units: SHS Score				
median (inter-quartile range (Q1-Q3))	10 (0 to 22)			

Statistical analyses

No statistical analyses for this end point

Secondary: to describe Quality of Life (impact on decision making in patients lives)

End point title	to describe Quality of Life (impact on decision making in patients lives)
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End point description:

Quality of life was evaluated using the Short-Health-Scale questionnaire, based on four questions using a visual analogue scale (with maximum score 100). For the question related to 'impact on decision-making in patients lives' higher scores mean more impact on daily activities.

End point type	Secondary
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End point timeframe:

Inclusion visit

End point values	Included patients for analysis			
Subject group type	Reporting group			
Number of subjects analysed	198			
Units: SHS score				
median (inter-quartile range (Q1-Q3))	1 (0 to 12)			

Statistical analyses

No statistical analyses for this end point

Secondary: to describe Quality of Life (worry about the disease)

End point title	to describe Quality of Life (worry about the disease)
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End point description:

Quality of life was evaluated using the Short-Health-Scale questionnaire, based on four questions using a visual analogue scale (with maximum score 100). For the question related to 'worry about the disease' higher scores mean more worry.

End point type	Secondary
End point timeframe:	
Inclusion Visit	

End point values	Included patients for analysis			
Subject group type	Reporting group			
Number of subjects analysed	198			
Units: SHS score				
median (inter-quartile range (Q1-Q3))	10 (0 to 32)			

Statistical analyses

No statistical analyses for this end point

Secondary: to describe quality of life (general well-being)

End point title	to describe quality of life (general well-being)
End point description:	
Quality of life was evaluated using the Short-Health-Scale questionnaire, based on four questions using a visual analogue scale (with maximum score 100). For the question related to 'general well-being' with lower scores mean better well-being.	
End point type	Secondary
End point timeframe:	
Inclusion visit	

End point values	Included patients for analysis			
Subject group type	Reporting group			
Number of subjects analysed	198			
Units: SHS score				
median (inter-quartile range (Q1-Q3))	11 (0 to 30)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

From signature of informed consent form up to completion of the study for that participant.

For SAE's up to 30 days after the study.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27
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Reporting groups

Reporting group title	UC patients
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Reporting group description: -

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: Only 3 adverse events occurred (in 3 patients). Therefore none of the adverse event meet the criterium of 5%.

Serious adverse events	UC patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 200 (0.50%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Infections and infestations			
Infectious syndrome			
subjects affected / exposed	1 / 200 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	UC patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 200 (0.00%)		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 October 2023	- Updated timelines for fecal calprotectin assessment and clarification on the conditions for the windows of the fecal calprotectin assessment and sigmoidoscopy - addition of possibility to capture routine biochemistry/fecal calprotectin results from maximum 1 month prior to screening/inclusion visit on the condition 5-ASA treatment remained stable in between. - Update duration of study for a patient (based on updated timeline for fecal calprotectin assessment) - Updated exclusion criteria to specify patients on UC-approved medication used for another indication should be excluded - Alignment between primary objective and primary endpoint with addition of biological remission - Additional clarifications for some study procedures - Changes to the Physician's questionnaire to capture information on potential change of current 5-ASA treatment

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported