Clinical trial results:
Investigation of the Faecal loss of Vedolizumab and its role in influencing serum drug levels, Outcomes and Response in ulcerative colitis

Summary

EudraCT number	2018-002794-21
Trial protocol	GB
Global end of trial date	29 October 2024

Results information

Result version number	v1 (current)
This version publication date	08 April 2026
First version publication date	08 April 2026
Summary attachment (see zip file)	FAVOUR CSR v2.0_Final 01Nov25 (FAVOUR CSR v2.0_Final 01Nov25.pdf)

Trial information

Trial identification

Sponsor protocol code	FAVOUR

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Guy's and St Thomas NHS Foundation Trust
Sponsor organisation address	Great Maze Pond, London, United Kingdom, SE1 9RT
Public contact	Peter Irving, Guy's & St Thomas NHS Foundation trust, 44 02071882499, peter.irving@gstt.nhs.uk
Scientific contact	Peter Irving, Guy's & St Thomas NHS Foundation trust, 44 02071882499, peter.irving@gstt.nhs.uk

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	29 October 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 June 2022
Global end of trial reached?	Yes
Global end of trial date	29 October 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine whether vedolizumab is present in significant quantities in the stool of patients receiving induction therapy with vedolizumab for active UC.

Protection of trial subjects:

Participants have the right to withdraw from the study at any time for any reason. The investigator also has the right to withdraw patients from the study drug in the event of inter-current illness, AEs, SAE's, SUSAR's, protocol violations, cure, administrative reasons or other reasons. It is understood by all concerned that an excessive rate of withdrawals can render the study un-interpretable; therefore, unnecessary withdrawal of patients should be avoided. Should a patient decide to withdraw from the study, all efforts will be made to report the reason for withdrawal as thoroughly as possible. Should a patient withdraw from study drug only, efforts will be made to continue to obtain follow-up data, with the permission of the patient. Because this is a non-interventional trial there won't be an interim analysis or premature termination of the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2018
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	United Kingdom: 36
Worldwide total number of subjects	36
EEA total number of subjects	36

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)	32
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment	
Recruitment details: -	
Pre-assignment	
Screening details: -	
Pre-assignment period milestones	
Number of subjects started	36
Number of subjects completed	36

Period 1	
Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded
Arms	
Arm title	Treatment Arm
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Vedolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab will be administered in the standard manner, with 300mg intravenous infusions at weeks 0, 2, 6 and 8 weekly thereafter (as is standard of care). Our study will include data collected during the first 14 weeks (4 infusions).

Number of subjects in period 1	Treatment Arm
Started	36
Completed	32
Not completed	4
UC non-response	3
Lost to follow-up	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall Trial

Reporting group description: -

Reporting group values	Overall Trial	Total	
Number of subjects	36	36	
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)	32	32	
From 65-84 years	4	4	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	13	13	
Male	23	23	

End points

End points reporting groups

Reporting group title	Treatment Arm

Reporting group description: -

Primary: Vedolizumab loss

End point title	Vedolizumab loss[1]

End point description:

End point type	Primary

End point timeframe:

Baseline - 14 Weeks

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: Please see uploaded report

End point values	Treatment Arm			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: Mean faecal vedolizumab level				
arithmetic mean (full range (min-max))				
Day 1	3.9 (0.0 to 64.7)			
Day 2	1.6 (0.0 to 21.6)			
Day 7	0.8 (0.0 to 5.8)			
Week 2	0.3 (0.1 to 1.3)			
Week 6	1.9 (0.0 to 49.4)			
Week 14	0.1 (0.0 to 1.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: SCCAI

End point title	SCCAI

End point description:

End point type	Secondary

End point timeframe:

Baseline - Week 14

End point values	Treatment Arm			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: Median SCCAI score				
arithmetic mean (full range (min-max))				
Baseline	5 (1 to 12)			
Week 2	4 (1 to 12)			
Week 6	3 (1 to 12)			
Week 14	1 (1 to 12)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: Baseline - Week 14	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	26.1

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

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: SAEs breakdown not present in CSR

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 December 2019	SA 01 - Changes to the RSI
08 March 2020	NSA02 - Protocol v2.0 Mar2020
04 November 2021	NSA3 - Protocol v3, Aug2021, SAP v2, 04Oct2021
22 November 2021	SA02 - RSI: section 4.8 of SmPC for Vedolizumab (Entyvio), dated 01Jun2021

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported