



Clinical trial results:

Study of the Golimumab Exposure-Response Relationship using Serum Trough Levels

Summary

EudraCT number	2017-001374-42
Trial protocol	GB
Global end of trial date	15 February 2021

Results information

Result version number	v1 (current)
This version publication date	12 November 2021
First version publication date	12 November 2021
Summary attachment (see zip file)	Clinical Study report (GO-LEVEL Clinical Study Report v1.0_25.8.21.pdf)

Trial information

Trial identification

Sponsor protocol code	3573
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03124121
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	Dr Peter Irving, Guy's and St Thomas' NHS Foundation Trust, +44 02071882499, peter.irving@gstt.nhs.uk
Scientific contact	Dr Peter Irving, Guy's and 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	15 February 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 September 2019
Global end of trial reached?	Yes
Global end of trial date	15 February 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To define a week 6 golimumab trough level concentration that predicts response at week 14.

Protection of trial subjects:

Patients are free to withdraw consent for study treatment and/or consent to participate in the study at any time and without the prejudice to further treatment. Patients who withdraw from study treatment, but are willing to continue to participate in the follow-up visits, should be followed according to the procedures outlined in the protocol.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 September 2017
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: 112
Worldwide total number of subjects	112
EEA total number of subjects	112

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)	109
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Potential participants were identified by members of the multidisciplinary direct care team. Potential participants were discussed at a multidisciplinary meeting where appropriateness for enrollment was assessed.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Golimumab Induction cohort
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	golimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients will receive standard golimumab induction treatment of 200 mg at week 0 and 100 mg at week 2, according to standard clinical practice. From week 6 maintenance treatment is started at 100 mg (\geq 80 kg) or 50 mg ($<$ 80 kg) every four weeks. Treatment will be continued until the supervising clinician makes the decision to withdraw treatment (exactly as the standard of care).

Arm title	Golimumab maintenance cohort
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	golimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients will receive standard golimumab induction treatment of 200 mg at week 0 and 100 mg at week 2, according to standard clinical practice. From week 6 maintenance treatment is started at 100 mg (\geq 80 kg) or 50 mg ($<$ 80 kg) every four weeks. Treatment will be continued until the supervising clinician makes the decision to withdraw treatment (exactly as the standard of care).

Number of subjects in period 1	Golimumab Induction cohort	Golimumab maintenance cohort
Started	42	70
Completed	38	66
Not completed	4	4
Disease progression	2	-
Adverse event, non-fatal	1	-
sample unsuitable for analysis	-	1
Protocol deviation	1	3

Baseline characteristics

Reporting groups

Reporting group title	Overall Trial
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Reporting group description: -

Reporting group values	Overall Trial	Total	
Number of subjects	112	112	
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)	109	109	
From 65-84 years	3	3	
85 years and over	0	0	
Overall	0	0	
Gender categorical			
Units: Subjects			
Female	47	47	
Male	65	65	

End points

End points reporting groups

Reporting group title	Golimumab Induction cohort
Reporting group description: -	
Reporting group title	Golimumab maintenance cohort
Reporting group description: -	

Primary: UC disease activity (SCCAI) at weeks 6 and 10

End point title	UC disease activity (SCCAI) at weeks 6 and 10 ^{[1][2]}
End point description:	

End point type	Primary
End point timeframe:	
baseline, week 6, week 10	

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: As this is a single arm study, EudraCT limitations would not allow the statistical analysis to be posted.

Please see the attached summary report for statistical analyses.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Cohorts were analysed separately

End point values	Golimumab Induction cohort			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: SCCAI score				
median (full range (min-max))				
baseline	8 (5 to 15)			
week 6	2 (0 to 12)			
week 10	1.5 (0 to 12)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Injection site reactions and SAEs collected from Day 0 to Day 98

Adverse event reporting additional description:

AE's will not be collected during the study period but will be managed as per the standard of care. Only injection-site reactions will be collected as AR's during the trial period. They will be managed as per the standard of care

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23
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Reporting groups

Reporting group title	golimumab
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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: AE's will not be collected during the study period but will be managed as per the standard of care. Only injection-site reactions will be collected as AR's during the trial period. They will be managed as per the standard of care.

Serious adverse events	golimumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 112 (3.57%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Gastrointestinal disorders			
Acute pancreatitis	Additional description: Azathioprine induced acute pancreatitis		
subjects affected / exposed	1 / 112 (0.89%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acute ulcerative colitis			
subjects affected / exposed	2 / 112 (1.79%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	1 / 112 (0.89%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Joint infection			

subjects affected / exposed	1 / 112 (0.89%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	golimumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 112 (0.00%)		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported