Clinical trial results:
A Monocenter, Open Label Study to Evaluate the Safety and Efficacy of Daratumumab in Combination with Standard Background Therapy in Participants with Moderate to Severe Systemic Lupus Erythematosus

Summary

EudraCT number	2021-000962-14
Trial protocol	DE
Global end of trial date	25 July 2024

Results information

Result version number	v1 (current)
This version publication date	10 April 2026
First version publication date	10 April 2026

Trial information

Trial identification

Sponsor protocol code	CCM-RNT-202101

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04810754
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Charitè - Universitätsmedizin Berlin
Sponsor organisation address	Charitéplatz 1, Berlin, Germany, 10117
Public contact	Rheumatologie - Studienabteilung, Charité - Universitätsmedizin Berlin, 0049 (0)30450513025, rheumastudien@charite.de
Scientific contact	Rheumatologie - Studienabteilung, Charité - Universitätsmedizin Berlin, 0049 (0)30450513025, rheumastudien@charite.de

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	11 August 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 July 2024
Global end of trial reached?	Yes
Global end of trial date	25 July 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to evaluate whether treatment with eight weekly subcutaneous injections of daratumumab is associated with a reduction of pathogenic serum anti-dsDNA antibodies in patients with moderate to severe SLE.

Primary objective of the LTE observational period ist to evaluate of the long-term safety of daratumumab, previously administered in the core study period, for the treatment of SLE;

Protection of trial subjects:

The study was conducted in accordance with the principles of the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 August 2021
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: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	10
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Ten patients were enrolled between August 2021 and January 2023 at one site in Germany

Pre-assignment

Screening details:

10 Patients with elevated anti -dsDNA antibodies in serum and active Systemic Lupus Erythematosus disease were screened an enrolled.

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:

This was a single-arm, open-label, phase 2 clinical trial.

Arms

Arm title	Daratumumab

Arm description:

single-arm, open-label,

Arm type	Experimental
Investigational medicinal product name	Daratumumab
Investigational medicinal product code	JNJ-54767414
Other name	Darzalex, EU/3/13/1153
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients received eight subcutaneous injections of 1800 mg daratumumab weekly, with dexamethasone as premedication (20mg for first two injections, then 10 mg)

Number of subjects in period 1	Daratumumab
Started	10
Completed	10

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	10	10	
Age categorical Units: Subjects			
Adults (18-64 years)	10	10	
Age continuous Units: years median full range (min-max)	 38 24 to 43	 -	
Gender categorical Units: Subjects			
Female	10	10	
Male	0	0	

End points

End points reporting groups

Reporting group title	Daratumumab
Reporting group description: single-arm, open-label,	

Primary: change anti-dsDNA level

End point title	change anti-dsDNA level[1]
End point description:	
End point type	Primary
End point timeframe: from baseline to week 12	

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: The primary and secondary outcome measures were analysed according to the intention-to-treat principle. For the primary endpoint analysis, the median is reported for anti-dsDNA antibody titres at baseline and at week 12. The change between the two assess ments was analysed using the non-parametric Wilcoxon signed-rank
test and the median difference with 95% CI estimate were calculated.For the immunological data, the Chi-Squared test, Kruskal-Wallis test with Dunn's test were computed, (charts)

End point values	Daratumumab			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: IU/ml				
median (confidence interval 95%)	109.6 (38.1 to 274.5)			

Attachments (see zip file)	primary and secondary endpoints/2021-000962-14 primary

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: overall trial	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	21
Reporting groups	
Reporting group title	Daratumumab

Reporting group description: -

Serious adverse events	Daratumumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Daratumumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 10 (90.00%)		
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 10 (40.00%)		
occurrences (all)	5		
Blood and lymphatic system disorders			
Immunoglobulin G<5g/L			
subjects affected / exposed	5 / 10 (50.00%)		
occurrences (all)	10		
General disorders and administration site conditions			
Injection related reaction			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	12		
Fatigue			

subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	3		
flu like symptoms			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Hot flush			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	4 / 10 (40.00%)		
occurrences (all)	8		
Diarrhoea			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	6		
Abdominal pain			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Pityriaisis rosae			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Infections and infestations			
Upper respiratory tract infection	Additional description: = Nasopharyngitis, Bronchitis, Sinusitis		
subjects affected / exposed	8 / 10 (80.00%)		
occurrences (all)	13		
COVID-19			

subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	3		
Herpes zoster			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Oral herpes			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Bacteriuria			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Urinary tract infection			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	2		
Gastroenteritis			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	3		

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/10427415