Clinical trial results:
Abatacept Bone Effects in Psoriatic Arthritis with Bone Biomarker – ABEPSA_BB

Summary

EudraCT number	2017-002793-39
Trial protocol	DE
Global end of trial date	16 September 2022

Results information

Result version number	v1 (current)
This version publication date	19 June 2024
First version publication date	19 June 2024

Trial information

Trial identification

Sponsor protocol code	0451

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Universitätsklinikum Erlangen
Sponsor organisation address	Maximiliansplatz 2, Erlangen, Germany, 91054
Public contact	Medizinische Klinik 3, Universitätsklinikum Erlangen, arnd.kleyer@extern.uk-erlangen.de
Scientific contact	Medizinische Klinik 3, Universitätsklinikum Erlangen, arnd.kleyer@extern.uk-erlangen.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	03 May 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 September 2022
Global end of trial reached?	Yes
Global end of trial date	16 September 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the effects of abatacept on erosive bone changes in patients with PsA for up to 24 weeks

Protection of trial subjects:

To limit the risk for side effects, abatacept was used according to the SmPC, furthermore vigorous inclusion and exclusion criteria as well as study visits over time did monitor the patients on drug

Background therapy:

-

Evidence for comparator: -

Actual start date of recruitment	15 January 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	Germany: 15
Worldwide total number of subjects	15
EEA total number of subjects	15

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)	11
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patient recruitment was performed in the outpatient and inpatient ward of the department of Internal Medicine 3, Universitätsklinikum Erlangen

Pre-assignment

Screening details:

Diagnosis of psoriasis arthritis acc. to the CASPAR criteria with active arthritis (> 2 swollen and tender joints) and at least 1 erosion at the MCP joint 2 o3 3 in imaging; indication for treatment with abatacept acc. to its SmPC

Period 1

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

Arms

Arm title	Treatment abatacept

Arm description:

treatment duration 24 weeks, 125 mg s.c. once weekly

Arm type	Experimental
Investigational medicinal product name	Abatacept
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen, Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

125 mg s.c. once weekly for 24 weeks

Number of subjects in period 1	Treatment abatacept
Started	15
Completed	8
Not completed	7
Physician decision	1
Adverse event, non-fatal	1
Lack of efficacy	5

Baseline characteristics

Reporting groups	
Reporting group title	Treatment

Reporting group description: -

Reporting group values	Treatment	Total	
Number of subjects	15	15	
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)	11	11	
From 65-84 years	4	4	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	8	8	
Male	7	7	
BMI Units: kilogram(s)/square metre			
arithmetic mean	30.68		
full range (min-max)	25.62 to 45.49	-	

End points

End points reporting groups

Reporting group title	Treatment abatacept
Reporting group description: treatment duration 24 weeks, 125 mg s.c. once weekly	

Primary: Change in bone erosion volume at the second and third MCP joint measured by HR-pQCT

End point title	Change in bone erosion volume at the second and third MCP joint measured by HR-pQCT[1]
End point description:	

End point type	Primary
End point timeframe: week 24 compared to baseline	

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 analyses planned (descriptive, only CI)

End point values	Treatment abatacept			
Subject group type	Reporting group			
Number of subjects analysed	7[2]			
Units: cubic millimeter				
arithmetic mean (confidence interval 95%)	0.71 (-1.53 to 2.95)			

Notes:

[2] - 2 early terminations, 5 non-responder, 1 non assessable due to destruction of the MCP joints

Statistical analyses

No statistical analyses for this end point

Secondary: Number of new erosions at second and thirt MCP joint at week 24 using HR-pQCT

End point title	Number of new erosions at second and thirt MCP joint at week 24 using HR-pQCT
End point description:	

End point type	Secondary
End point timeframe: week 24	

End point values	Treatment abatacept			
Subject group type	Reporting group			
Number of subjects analysed	7[3]			
Units: number of erosions	0			

Notes:

[3] - 2 early terminations, 5 non-responder, 1 non assessable due to destruction of the MCP joints

Statistical analyses

No statistical analyses for this end point

Secondary: Number of new osteophytes in MCP joints at week 24 using HR-pQCT

End point title	Number of new osteophytes in MCP joints at week 24 using HR-pQCT

End point description:

End point type	Secondary

End point timeframe:

week 24

End point values	Treatment abatacept			
Subject group type	Reporting group			
Number of subjects analysed	7[4]			
Units: number of new osteophytes	0			

Notes:

[4] - 2 early terminations, 5 non-responder, 1 non assessable due to destruction of the MCP joints

Statistical analyses

No statistical analyses for this end point

Secondary: Number of new erosions at week 24 using hand MRI

End point title	Number of new erosions at week 24 using hand MRI

End point description:

End point type	Secondary

End point timeframe:

week 24

End point values	Treatment abatacept			
Subject group type	Reporting group			
Number of subjects analysed	13[5]			
Units: number of erosions	1			

Notes:

[5] - 2 Early terminations

Statistical analyses

No statistical analyses for this end point

Secondary: Change in tenosynovitis score using hand MRI

End point title	Change in tenosynovitis score using hand MRI

End point description:

End point type	Secondary

End point timeframe:

week 24 compared to baseline

End point values	Treatment abatacept			
Subject group type	Reporting group			
Number of subjects analysed	13[6]			
Units: none				
arithmetic mean (confidence interval 95%)	-1.22 (-2.79 to 0.34)			

Notes:

[6] - 2 Early terminations

Statistical analyses

No statistical analyses for this end point

Secondary: Change in PSAMRIS using hand MRI

End point title	Change in PSAMRIS using hand MRI

End point description:

End point type	Secondary

End point timeframe:

week 24 compared to baseline

End point values	Treatment abatacept			
Subject group type	Reporting group			
Number of subjects analysed	13[7]			
Units: none				
arithmetic mean (confidence interval 95%)	2.66 (-1.01 to 6.34)			

Notes:

[7] - 2 Early terminations

Statistical analyses

No statistical analyses for this end point

Secondary: Change in synovitis score using hand MRI

End point title	Change in synovitis score using hand MRI

End point description:

End point type	Secondary

End point timeframe:

week 24 compared to baseline

End point values	Treatment abatacept			
Subject group type	Reporting group			
Number of subjects analysed	13[8]			
Units: none				
arithmetic mean (confidence interval 95%)	1.99 (0.54 to 3.44)			

Notes:

[8] - 2 Early terminations

Statistical analyses

No statistical analyses for this end point

Secondary: Change in DAS28 (ESR)

End point title	Change in DAS28 (ESR)

End point description:

End point type	Secondary

End point timeframe:

week 24 compared to baseline

End point values	Treatment abatacept			
Subject group type	Reporting group			
Number of subjects analysed	13[9]			
Units: none				
arithmetic mean (confidence interval 95%)	-1.93 (-2.44 to -1.41)			

Notes:

[9] - 2 Early terminations

Statistical analyses

No statistical analyses for this end point

Secondary: Change in DAPSA

End point title	Change in DAPSA

End point description:

End point type	Secondary

End point timeframe:

week 24 compared to baseline

End point values	Treatment abatacept			
Subject group type	Reporting group			
Number of subjects analysed	13[10]			
Units: none				
arithmetic mean (confidence interval 95%)	-18.6 (-24.48 to -12.73)			

Notes:

[10] - 2 Early terminations

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HAQ-DI

End point title	Change in HAQ-DI

End point description:

End point type	Secondary

End point timeframe:

week 24 compared to baseline

End point values	Treatment abatacept			
Subject group type	Reporting group			
Number of subjects analysed	13[11]			
Units: none				
arithmetic mean (confidence interval 95%)	-0.12 (-0.43 to 0.18)			

Notes:

[11] - 2 Early terminations

Statistical analyses

No statistical analyses for this end point

Secondary: Change in SPARCC

End point title	Change in SPARCC

End point description:

End point type	Secondary

End point timeframe:

week 24 compared to baseline

End point values	Treatment abatacept			
Subject group type	Reporting group			
Number of subjects analysed	13[12]			
Units: none				
arithmetic mean (confidence interval 95%)	-1.15 (-2.4 to 0.09)			

Notes:

[12] - 2 Early terminations

Statistical analyses

No statistical analyses for this end point

Secondary: Change in PSAID

End point title	Change in PSAID

End point description:

End point type	Secondary

End point timeframe:

week 24 compared to baseline

End point values	Treatment abatacept			
Subject group type	Reporting group			
Number of subjects analysed	13[13]			
Units: none				
arithmetic mean (confidence interval 95%)	-0.79 (-2.04 to 0.46)			

Notes:

[13] - 2 Early terminations

Statistical analyses

No statistical analyses for this end point

Secondary: Change in PASI

End point title	Change in PASI

End point description:

End point type	Secondary

End point timeframe:

week 24 compared to baseline

End point values	Treatment abatacept			
Subject group type	Reporting group			
Number of subjects analysed	13[14]			
Units: none				
arithmetic mean (confidence interval 95%)	0.03 (-2.79 to 2.85)			

Notes:

[14] - 2 Early terminations

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information
Timeframe for reporting adverse events:
V1 (enrolment) until V5 (EoS, week 28)
Adverse event reporting additional description:
AE reporting continuously during the treatment period and for a minimum of 4 weeks after the last IMP administration

Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups	
Reporting group title	Safety Analysis Set
Reporting group description:	
all subjects treated with at least 1 dose of IMP	

Serious adverse events	Safety Analysis Set		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 15 (6.67%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Radius fracture			
subjects affected / exposed	1 / 15 (6.67%)		
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	Safety Analysis Set		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 15 (60.00%)		
Investigations			
Blood glucose abnormal			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Electrocardiogram T wave abnormal			

subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Prostatic specific antigen abnormal			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	2		
Injury, poisoning and procedural complications			
Immunisation reaction			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Vascular disorders			
Hypertensive crisis			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	2		
Cardiac disorders			
Tachycardia			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		

Pustular psoriasis subjects affected / exposed occurrences (all) Skin lesion subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1 1 / 15 (6.67%) 1		
Infections and infestations COVID-19 subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1 2 / 15 (13.33%) 2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 October 2019	Change Investigator, Update SmPC
16 April 2020	Additional Inclusion criterion reg. wash out times for pre-treatment with b/tsDMARDs; SF-36 questionnaire deleted
29 December 2020	Inclusion/Exclusion criteria specified (localisation of erosions; cDMARD intolerance etc.)

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.

Early termination due to poor recruitment; number of subjects limited

Notes: