Clinical trial results:
Evaluation of inflammatory and structural joint damage in patients with psoriasis and psoriatic arthritis treated with secukinumab: A phase 2, single arm, single centre mode of action study (Psoriasis-Arthritis & Bone Program, PSARTROS)

Summary

EudraCT number	2014-004798-17
Trial protocol	DE
Global end of trial date	18 September 2017

Results information

Result version number	v1 (current)
This version publication date	15 July 2020
First version publication date	15 July 2020

Trial information

Trial identification

Sponsor protocol code	CAIN457F2301T

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02483234
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, georg.schett@uk-erlangen.de
Scientific contact	Medizinische Klinik 3, Universitätsklinikum Erlangen, georg.schett@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	28 June 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 June 2017
Global end of trial reached?	Yes
Global end of trial date	18 September 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Effect of secukinumab on inflammatory and structural signs and Symptoms (PsAMRIS score)

Protection of trial subjects:

Routine lab Control, physical examination and AE assessment at regular intervals; discontinuation of Treatment in case of any AE that is not compatible with IMP Administration, life-threatening infections, malignancies, pregnancy or any lab abnormalities that are deemed to place the subject at a safety Risk

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 June 2015
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: 40
Worldwide total number of subjects	40
EEA total number of subjects	40

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)	33
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

IC: adequate wash-out time for pretreatment with TNFInhibitors / ustekinumab; PsA subj: moderate to severe PsA with Symptoms for at least 6 months / Psoriasis subj: inflamm. or structural lesions/erosions in MRI/HR-pQCT
48 subj assessed for eligibility, 8 subj excluded, 40 included

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Psoriasis

Arm description:

Subjects with Psoriasis (without PsA)

Arm type	Experimental
Investigational medicinal product name	Secukinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300mg s.c. week 0,1,2,3,4,8,12,16,20

Arm title	Psoriasis Arthritis

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Secukinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300mg s.c. week 0,1,2,3,4,8,12,16,20

Number of subjects in period 1	Psoriasis	Psoriasis Arthritis
Started	20	20
Completed	19	17
Not completed	1	3
Consent withdrawn by subject	-	1
Adverse event, non-fatal	-	1

Lack of efficacy	1	1

Period 2	
Period 2 title	Analysis period
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	Yes
Arm title	Psoriasis
Arm description: Subjects with Psoriasis (without PsA)	
Arm type	Experimental
Investigational medicinal product name	Secukinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: 300mg s.c. week 0,1,2,3,4,8,12,16,20	
Arm title	Psoriasis Arthritis
Arm description: Subjects with PsA	
Arm type	Experimental
Investigational medicinal product name	Secukinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: 300mg s.c. week 0,1,2,3,4,8,12,16,20	

Number of subjects in period 2	Psoriasis	Psoriasis Arthritis
Started	19	17
Completed	18	17
Not completed	1	0
unable to perform MRI	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Psoriasis
Reporting group description: Subjects with Psoriasis (without PsA)	
Reporting group title	Psoriasis Arthritis
Reporting group description: -	

Reporting group values	Psoriasis	Psoriasis Arthritis	Total
Number of subjects	20	20	40
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
median	49.5	50.5	
inter-quartile range (Q1-Q3)	42.8 to 59	44 to 59	-
Gender categorical Units: Subjects			
Female	6	12	18
Male	14	8	22
Pre-treatment with bDMARDs Units: Subjects			
positive	0	9	9
negative	20	11	31
Concomitant cDMARDs Units: Subjects			
positive	0	8	8
negative	20	12	32
PDUS synovitis Units: Subjects			
positive	0	14	14
negative	0	6	6
not recorded	20	0	20
Disease duration Units: year			
median	14	5.5	
inter-quartile range (Q1-Q3)	5 to 20	1.25 to 12.75	-

TJC			
Units: unit(s)			
median	0	10	
inter-quartile range (Q1-Q3)	0 to 3.75	6.25 to 20	-
SJC			
Units: unit(s)			
median	0	4	
inter-quartile range (Q1-Q3)	0 to 0	3 to 5.75	-
PASI			
Units: unit(s)			
median	6.8	0.4	
inter-quartile range (Q1-Q3)	3.5 to 18.6	0.2 to 1.9	-
BSA			
Units: percent			
median	10.9	0.4	
inter-quartile range (Q1-Q3)	3.6 to 20.3	0.2 to 1.5	-
total PSAMRIS			
Units: unit(s)			
median	4	5.5	
inter-quartile range (Q1-Q3)	0.75 to 7.25	3 to 19.5	-
HR-pQCT erosion number			
Units: unit(s)			
median			
inter-quartile range (Q1-Q3)			-
PDSU OMERACT global			
Units: unit(s)			
median		5	
inter-quartile range (Q1-Q3)		3 to 11	-

Subject analysis sets

Subject analysis set title	Psoriasis PP week 0
Subject analysis set type	Per protocol

Subject analysis set description:

All subjects with Psoriasis receiving Treatment with secukinumab for 24 weeks, PSAMRIS score at week 24 available

Subject analysis set title	Psoriasis Arthritis PP week 0
Subject analysis set type	Per protocol

Subject analysis set description:

All subjects with Psoriasis Arthritis receiving Treatment with secukinumab for 24 weeks, PSAMRIS score at week 24 available

Reporting group values	Psoriasis PP week 0	Psoriasis Arthritis PP week 0	
Number of subjects	18	17	
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			

Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years median inter-quartile range (Q1-Q3)	 47	 50	
Gender categorical Units: Subjects			
Female Male	5 13	1 7	
Pre-treatment with bDMARDs Units: Subjects			
positive negative			
Concomitant cDMARDs Units: Subjects			
positive negative			
PDUS synovitis Units: Subjects			
positive negative not recorded	 18	12 5 0	
Disease duration Units: year median inter-quartile range (Q1-Q3)			
TJC Units: unit(s) median inter-quartile range (Q1-Q3)	 0 0 to 3.75	 10 6 to 16.5	
SJC Units: unit(s) median inter-quartile range (Q1-Q3)	 0 0 to 0	 4 3 to 7	
PASI Units: unit(s) median inter-quartile range (Q1-Q3)	 6.9 3.5 to 18.6	 0.4 0.2 to 2.3	
BSA Units: percent median inter-quartile range (Q1-Q3)	 9.2 4.3 to 18.1	 0.3 0.2 to 1.5	
total PSAMRIS Units: unit(s) median inter-quartile range (Q1-Q3)	 4 0.75 to 7.25	 6 3.5 to 18	
HR-pQCT erosion number			

Units: unit(s)			
median	1	2	
inter-quartile range (Q1-Q3)	0 to 1.75	0.5 to 4.5	
PDSU OMERACT global			
Units: unit(s)			
median		5	
inter-quartile range (Q1-Q3)		3 to 11	

End points

End points reporting groups

Reporting group title	Psoriasis
Reporting group description: Subjects with Psoriasis (without PsA)	
Reporting group title	Psoriasis Arthritis
Reporting group description: -	
Reporting group title	Psoriasis
Reporting group description: Subjects with Psoriasis (without PsA)	
Reporting group title	Psoriasis Arthritis
Reporting group description: Subjects with PsA	
Subject analysis set title	Psoriasis PP week 0
Subject analysis set type	Per protocol
Subject analysis set description: All subjects with Psoriasis receiving Treatment with secukinumab for 24 weeks, PSAMRIS score at week 24 available	
Subject analysis set title	Psoriasis Arthritis PP week 0
Subject analysis set type	Per protocol
Subject analysis set description: All subjects with Psoriasis Arthritis receiving Treatment with secukinumab for 24 weeks, PSAMRIS score at week 24 available	

Primary: Change in PSAMRIS score - Psoriasis Arthritis

End point title	Change in PSAMRIS score - Psoriasis Arthritis
End point description: PSAMRIS score week 24 compared to PSAMRIS score week 0 in PP-subjects with Psoriasis Arthritis	
End point type	Primary
End point timeframe: week 0 to week 24	

End point values	Psoriasis Arthritis	Psoriasis Arthritis PP week 0		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	17	17		
Units: unit(s)				
median (inter-quartile range (Q1-Q3))	4 (1 to 13.5)	6 (3.5 to 18)		

Statistical analyses

Statistical analysis title	Change in PSAMRIS score - Psoriasis Arthritis

Statistical analysis description:

The Wilcoxon signed-rank test for paired comparisons between baseline and week 24 was used.

Comparison groups	Psoriasis Arthritis v Psoriasis Arthritis PP week 0
Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.039
Method	wilcoxon signed-rank test

Primary: Change in PSAMRIS score - Psoriasis

End point title	Change in PSAMRIS score - Psoriasis

End point description:

PSAMRIS score week 24 compared to PSAMRIS score week 0 in PP-subjects with Psoriasis

End point type	Primary

End point timeframe:

week 0 to week 24

End point values	Psoriasis	Psoriasis PP week 0		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	18[1]	18		
Units: unit(s)				
median (inter-quartile range (Q1-Q3))	3 (0 to 6)	5 (1 to 8)		

Notes:

[1] - 1 subject was excluded from all endpoint analyses as Primary endpoint could not be analysed

Statistical analyses

Statistical analysis title	Change in PSAMRIS score - Psoriasis

Statistical analysis description:

The Wilcoxon signed-rank test for paired comparisons between baseline and week 24 was used.

Comparison groups	Psoriasis v Psoriasis PP week 0
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	Wilcoxon signed-rank test

Secondary: Change in PASI - Psoriasis Arthritis

End point title	Change in PASI - Psoriasis Arthritis

End point description:

PASI score week 24 compared to PASI score week 0 in PP-subjects with Psoriasis Arthritis

End point type	Secondary

End point timeframe:

week 0 to week 24

End point values	Psoriasis Arthritis	Psoriasis Arthritis PP week 0		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	17	17		
Units: unit(s)				
median (inter-quartile range (Q1-Q3))	0.1 (0 to 1.3)	0.4 (0.2 to 2.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: ACR20 response - Psoriasis Arthritis

End point title	ACR20 response - Psoriasis Arthritis

End point description:

End point type	Secondary

End point timeframe:

week 24

End point values	Psoriasis Arthritis			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: subjects	14			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in DAS28-ESR - Psoriasis Arthritis

End point title	Change in DAS28-ESR - Psoriasis Arthritis

End point description:

DAS28-ESR score week 24 compared to DAS28-ESR score week 0 in PP-subjects with Psoriasis Arthritis

End point type	Secondary

End point timeframe:

week 0 to week 24

End point values	Psoriasis Arthritis	Psoriasis Arthritis PP week 0		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	17	17		
Units: unit(s)				
median (inter-quartile range (Q1-Q3))	2.93 (2.01 to 3.70)	4.93 (4.08 to 5.74)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in PSAID - Psoriasis

End point title	Change in PSAID - Psoriasis
End point description:	
PSAID score week 24 compared to PSAID score week 0 in PP-subjects with Psoriasis	
End point type	Secondary
End point timeframe:	
week 0 to week 24	

End point values	Psoriasis	Psoriasis PP week 0		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	18[2]	18		
Units: unit(s)				
median (inter-quartile range (Q1-Q3))	1.35 (0.2 to 2.35)	3.5 (1.65 to 4.7)		

Notes:

[2] - 1 subject was excluded from all endpoint analyses as Primary endpoint could not be analysed

Statistical analyses

No statistical analyses for this end point

Secondary: Change in DLQI - Psoriasis

End point title	Change in DLQI - Psoriasis
End point description:	
DLQI score week 24 compared to DLQI score week 0 in PP-subjects with Psoriasis	
End point type	Secondary
End point timeframe:	
week 0 to week 24	

End point values	Psoriasis	Psoriasis PP week 0		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	18[3]	18		
Units: unit(s)				
median (inter-quartile range (Q1-Q3))	1.5 (0.75 to 5.75)	10 (5 to 15)		

Notes:

[3] - 1 subject was excluded from all endpoint analyses as Primary endpoint could not be analysed

Statistical analyses

No statistical analyses for this end point

Secondary: Change in PDUS OMERACT global - Psoriasis Arthritis

End point title	Change in PDUS OMERACT global - Psoriasis Arthritis

End point description:

PDUS OMERACT global week 24 compared to PDUS OMERACT global week 0 in PP-subjects with Psoriasis Arthritis

End point type	Secondary

End point timeframe:

week 24

End point values	Psoriasis Arthritis	Psoriasis Arthritis PP week 0		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	17	17		
Units: unit(s)				
median (inter-quartile range (Q1-Q3))	1 (0 to 5)	5 (3 to 11)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HR-pQCT enthesiophytes - Psoriasis Arthritis

End point title	Change in HR-pQCT enthesiophytes - Psoriasis Arthritis

End point description:

HR-pQCT enthesiophytes week 24 compared to HR-pQCT enthesiophytes week 0 in PP-subjects with Psoriasis Arthritis,
proliferation grading: grade 0 = absent; grade 1 = maximum heigth <= 4mm; grade 2 = maximum height > 4mm; grade 3 = diffuse osteoproliferation

End point type	Secondary

End point timeframe:

week 24

End point values	Psoriasis Arthritis	Psoriasis Arthritis PP week 0		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	17	17		
Units: unit(s)				
median (inter-quartile range (Q1-Q3))	2 (1.5 to 2)	2 (1 to 2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HR-pQCT erosion number - Psoriasis Arthritis

End point title	Change in HR-pQCT erosion number - Psoriasis Arthritis

End point description:

Change in HR-pQCT Erosion number week 24 compared to HR-pQCT erolsion number week 0 in PP-subjects with Psoriasis Arthritis

End point type	Secondary

End point timeframe:

week 24 compared to week 0

End point values	Psoriasis Arthritis	Psoriasis Arthritis PP week 0		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	17	17		
Units: unit(s)				
median (inter-quartile range (Q1-Q3))	2 (1 to 4)	2 (0.5 to 4.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in PASI - Psoriasis

End point title	Change in PASI - Psoriasis

End point description:

PASI score week 24 compared to PASI score week 0 in PP-subjects with Psoriasis

End point type	Secondary

End point timeframe:

week 24 compared to week 0

End point values	Psoriasis	Psoriasis PP week 0		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	18[4]	18		
Units: unit(s)				
median (inter-quartile range (Q1-Q3))	0.4 (0 to 1.5)	6.9 (3.5 to 18.6)		

Notes:

[4] - 1 subject was excluded from analysis as no Primary endpoint available

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HR-pQCT enthesiophytes - Psoriasis

End point title	Change in HR-pQCT enthesiophytes - Psoriasis

End point description:

HR-pQCT enthesiophytes week 24 compared to HR-pQCT enthesiophytes week 0 in PP-subjects with Psoriasis

End point type	Secondary

End point timeframe:

week 24 compared to week 0

End point values	Psoriasis	Psoriasis PP week 0		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	18[5]	18		
Units: unit(s)				
median (inter-quartile range (Q1-Q3))	1 (0 to 1.75)	1 (0 to 1.75)		

Notes:

[5] - 1 subject was excluded from endpoint analyses as no Primary endpoint was available

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HR-pQCT erosion number - Psoriasis

End point title	Change in HR-pQCT erosion number - Psoriasis

End point description:

Change in HR-pQCT Erosion number week 24 compared to HR-pQCT erolsion number week 0 in PP-subjects with Psoriasis

End point type	Secondary

End point timeframe:

week 24 compared to week 0

End point values	Psoriasis	Psoriasis PP week 0		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	18[6]	18		
Units: unit(s)				
median (inter-quartile range (Q1-Q3))	1 (0 to 1.75)	1 (0 to 1.75)		

Notes:

[6] - 1 subject was excluded from all endpoint analyses as Primary endpoint was not available

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: From the time of enrolment (signature informed consent) until EoS visit (week 24)	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	23
Reporting groups	
Reporting group title	All subjects
Reporting group description: Subjects with PsA or Psoriasis	

Serious adverse events	All subjects		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 40 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	All subjects		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	39 / 40 (97.50%)		
Investigations			
Liver function test increased			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	3		
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 40 (10.00%)		
occurrences (all)	5		
General disorders and administration			

site conditions Fatigue subjects affected / exposed occurrences (all) Injection site haematoma subjects affected / exposed occurrences (all)	 2 / 40 (5.00%) 2 1 / 40 (2.50%) 2		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all)	 5 / 40 (12.50%) 5 2 / 40 (5.00%) 2		
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all)	 5 / 40 (12.50%) 7		
Renal and urinary disorders Haematuria subjects affected / exposed occurrences (all)	 2 / 40 (5.00%) 2		
Endocrine disorders Hyperparathyroidism subjects affected / exposed occurrences (all)	 2 / 40 (5.00%) 2		
Musculoskeletal and connective tissue disorders Bursitis subjects affected / exposed occurrences (all) Arthralgia subjects affected / exposed occurrences (all)	 2 / 40 (5.00%) 3 4 / 40 (10.00%) 4		
Infections and infestations Conjunctivitis subjects affected / exposed occurrences (all)	 2 / 40 (5.00%) 2		

Nasopharyngitis subjects affected / exposed occurrences (all)	15 / 40 (37.50%) 21		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 40 (5.00%) 3		
Sinusitis subjects affected / exposed occurrences (all)	4 / 40 (10.00%) 4		
Genital infection fungal subjects affected / exposed occurrences (all)	2 / 40 (5.00%) 2		
Oral herpes subjects affected / exposed occurrences (all)	2 / 40 (5.00%) 4		
Nail infection subjects affected / exposed occurrences (all)	2 / 40 (5.00%) 2		
Urinary tract infection subjects affected / exposed occurrences (all)	2 / 40 (5.00%) 3		
Metabolism and nutrition disorders Hyperuricaemia subjects affected / exposed occurrences (all)	2 / 40 (5.00%) 2		
Vitamin D deficiency subjects affected / exposed occurrences (all)	4 / 40 (10.00%) 4		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 May 2015	Protocol v2.0

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported