Clinical trial results:
Efficacy of Tofacitinib in Reduction of Inflammation Detected on MRI in Patients with Psoriatic ArthritiS PresenTing with Axial InvOlvement - a Randomized, Double-Blind, Placebo-Controlled, Multicenter Trial (PASTOR)

Summary

EudraCT number	2018-004254-22
Trial protocol	DE
Global end of trial date	02 May 2024

Results information

Result version number	v1 (current)
This version publication date	12 June 2025
First version publication date	12 June 2025
Summary attachment (see zip file)	bar-charts_primary and secondary endpoints (PASTOR_Efficacy analysis_primary and secondary endpoints.pdf)

Trial information

Trial identification

Sponsor protocol code	PASTOR2018

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04062695
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Charité Universitätsmedizin Berlin
Sponsor organisation address	Cahritéplatz 1, Berlin, Germany, 10117
Public contact	PD Dr. med. Fabian Proft and PD Dr. Hildrun Haibel, Charité Universitätsmedizin Berlin, Campus Benjamin Franklin Medical Department I, Rheumatology, 49 30 450514582, fabian.proft@charite.de
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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	20 November 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 May 2024
Global end of trial reached?	Yes
Global end of trial date	02 May 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Improvement of the total Berlin MRI score for sacroiliac joints and spine as compared to baseline after 12 weeks of therapy with Tofacitinib or placebo.

Protection of trial subjects:

The study was conducted in accordance with the principles of the Declaration of Helsinki (1996).

Background therapy:

Psoriatic arthritis (PsA) is a chronic inflammatory disease associated with psoriasis, which is attributed to the group of spondyloarthritides (SpA) and is characterized by the presence of synovitis, enthesitis, dactylitis, and by axial involvement.There is a considerable overlap of PsA with axial SpA in terms of pathophysiology, diagnosis, and classification, however, patients with PsA can also be classified as axial SpA on the basis of their clinical presentation. There are also significant differences between axial PsA and axial SpA in genetics, radiographic features, age at disease onset and clinical progression over time. According to treatment guidelines for axial PsA, the main treatment options in patients with PsA presenting with axial involvement are NSAIDs. If they fail to show sufficient efficacy tumour necrosis factor (TNF) inhibitors or IL-17 inhibitors and newerdays JAK-inhibitors may be considered.
The aim of this study was to investigate the efficacy and safety of the JAK inhibitor Tofactinib in axPsA.

Evidence for comparator: -

Actual start date of recruitment	01 April 2020
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: 26
Worldwide total number of subjects	26
EEA total number of subjects	26

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)	26
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited between 12/09/2020 to 04/08/2023 in xx study sites in Germany.

Pre-assignment

Screening details:

In total 42 patients with diagnose of PsA, presence of chronic (duration ≥3 months) back pain,BASDAI value of ≥4 and back pain score (BASDAI Question 2) of ≥4, presence of active inflammation of sreening MRI...were screened, 16 patients were failed screening and 26 patients received the baseline visit.

Period 1

Period 1 title	double-blind period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Data analyst, Carer, Subject

Arms

Are arms mutually exclusive?	No
Arm title	Tofacitinib 5mg

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Tofacitinib
Investigational medicinal product code	SUB33105
Other name	XELJANZ, TOFACITINIB CITRATE
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

5mg orally twice daily for a 12-week period. After week 12 began the open label period, patients were to receive Tofacitinib 5mg orally twice daily for another 12 weeks.

Arm title	Placebo 12 weeks

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Patients received Placebo orally twice daily for a 12-week period.

Number of subjects in period 1	Tofacitinib 5mg	Placebo 12 weeks
Started	14	12
Completed	14	12

Baseline characteristics

Reporting groups	
Reporting group title	Tofacitinib 5mg
Reporting group description: -	
Reporting group title	Placebo 12 weeks
Reporting group description: -	

Reporting group values	Tofacitinib 5mg	Placebo 12 weeks	Total
Number of subjects	14	12	26
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	40	41	
full range (min-max)	19 to 54	19 to 63	-
Gender categorical Units: Subjects			
Female	6	4	10
Male	8	8	16
Symptom duration (back pain) Units: years			
arithmetic mean	8	10	
full range (min-max)	1 to 27	1 to 22	-
Duration since Diagnosis Units: years			
arithmetic mean	3.17	3.05	
standard deviation	± 3.72	± 2.27	-
Body weight Units: kg			
arithmetic mean	78	91	
full range (min-max)	58 to 97	63 to 116	-
Number of swollen joints Units: number			
arithmetic mean	3	1.92	
standard deviation	± 5.57	± 3.32	-
BASMI (0-10)			
Bath Ankylosing Spondylitis Metrology Index -Improvement of axial mobility			
Units: score			
arithmetic mean	3.14	3.23	
standard deviation	± 1.02	± 1.18	-
BASDAI			
BASDAI= Bath Ankylosing Spondylitis Disease Activity Index;			
Units: Score			
arithmetic mean	6.1	6.25	
standard deviation	± 1.39	± 1.35	-
BASFI			
BASFI= Bath Ankylosing Spondylitis Disease Functional Index			

Units: score			
arithmetic mean	5.34	4.92	
standard deviation	± 1.51	± 1.7	-
PASI			
PASI = Psoriasis Area Severity Index			
Units: Score			
arithmetic mean	4	3.1	
standard deviation	± 6.3	± 4	-
HAQ-DI			
HAQ-DI= Health Assessment Questionnaire Disability Index			
Units: score			
arithmetic mean	1.15	1.01	
standard deviation	± 0.39	± 0.41	-
CRP			
CRP= C-reactive protein (reference range < 5mg/L)			
Units: mg/l			
arithmetic mean	14	9	
standard deviation	± 25	± 8	-
MASES			
Maastricht Ankylosing Spondylitis Enthesitis Score =MASES			
Units: Score			
arithmetic mean	1.64	3.33	
standard deviation	± 2.17	± 3.34	-
Physician Global			
physician global assessment on the NRS			
Units: score			
arithmetic mean	6.21	5.75	
standard deviation	± 2.49	± 1.71	-

End points

End points reporting groups

Reporting group title	Tofacitinib 5mg
Reporting group description: -	
Reporting group title	Placebo 12 weeks
Reporting group description: -	

Primary: change Berlin MRI score for spine

End point title	change Berlin MRI score for spine[1]
End point description:	
Efficacy of the therapy in reducing inflammation in spine on MRI in patients with active axial PsA was to be assessed byBerlin MRI scoring method (range for osteitis 0-69 for the spine).	
End point type	Primary
End point timeframe:	
at week 12 as 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: In order to demonstrate a significant difference between Tofacitinib and placebo groups using the two-sided T-Test for mean difference with the power of 80% and alpha=0.05 (anticipated standard deviation = 3.0), at least 74 patients (37 per arm) should be included in the analysis set.
In this trial only 26 patients were included. No statistical analysis were performed.

End point values	Tofacitinib 5mg	Placebo 12 weeks		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	12		
Units: score				
arithmetic mean (standard deviation)				
baseline	4.6 (± 8.3)	2.9 (± 6.2)		
12 weeks	1.6 (± 3.6)	2.6 (± 6.2)		

Statistical analyses

No statistical analyses for this end point

Primary: change Berlin MRI score for sacroiliac joint (SIJ)

End point title	change Berlin MRI score for sacroiliac joint (SIJ)[2]
End point description:	
End point type	Primary
End point timeframe:	
compared to baseline after 12 weeks of therapy with Tofacitinib or Placebo	

Notes:

[2] - 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: In order to demonstrate a significant difference between Tofacitinib and placebo groups using the two-sided T-Test for mean difference with the power of 80% and alpha=0.05 (anticipated

standard deviation = 3.0), at least 74 patients (37 per arm) should be included in the analysis set. In this trial only 26 patients were included. No statistical analysis were performed.

End point values	Tofacitinib 5mg	Placebo 12 weeks		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	12		
Units: Score				
arithmetic mean (standard deviation)				
baseline	3.3 (± 4.2)	5.5 (± 4.8)		
12 weeks	1.8 (± 3.1)	4.5 (± 4.7)		

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	21.0

Reporting groups	
Reporting group title	Placebo to Tofacitinib
Reporting group description: -	
Reporting group title	Tofacitinib
Reporting group description: -	

Serious adverse events	Placebo to Tofacitinib	Tofacitinib	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 12 (16.67%)	0 / 14 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Musculoskeletal and connective tissue disorders			
Polyarthralgia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
pneumonia associated to COVID-19			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo to Tofacitinib	Tofacitinib	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 12 (100.00%)	10 / 14 (71.43%)	

Investigations			
Transaminases increased			
subjects affected / exposed	2 / 12 (16.67%)	2 / 14 (14.29%)	
occurrences (all)	2	2	
Injury, poisoning and procedural complications			
Traumatic chest injury NOS			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Vaccination adverse reaction			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
Hypertensive crisis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Migraine			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Headache			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Concentration impaired			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
flu-like symptoms			
subjects affected / exposed	3 / 12 (25.00%)	0 / 14 (0.00%)	
occurrences (all)	4	0	
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Pain			

subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Diarrhea			
subjects affected / exposed	2 / 12 (16.67%)	0 / 14 (0.00%)	
occurrences (all)	2	0	
Gastroenteritis/ Gastritis			
subjects affected / exposed	0 / 12 (0.00%)	2 / 14 (14.29%)	
occurrences (all)	0	2	
Food poisoning			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Nausea			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	
occurrences (all)	2	0	
Reproductive system and breast disorders			
Prostatitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Dry cough			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Degeneration of cervical intervertebral disc			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Psoriatic spondylitis			
subjects affected / exposed	1 / 12 (8.33%)	1 / 14 (7.14%)	
occurrences (all)	1	1	
Metatarsalgia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Infections and infestations			

Upper respiratory infection (Covid-19)			
subjects affected / exposed	2 / 12 (16.67%)	1 / 14 (7.14%)	
occurrences (all)	2	2	
Bronchitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
chronic sinusitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Herpes labialis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Abscess jaw			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 March 2020	Update protocol version 2.1 from 09/03/2020- (update IB to SmPc Xeljanz film-coated tablets, adjustment of inclusion criteria: Age limit <65 years, and selection of patients based on number, age, gender)
20 October 2021	Update protocol version 3.0 dated 14/10/2021 (update IB to SmPc Tofacitinal and change ICF)

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.

Only 26 of the originally 80 planned patients were included. The reason for this was the black box warning for tofacitinib not to be used as first-line therapy in patients with cardiovascular risk and the COVID-19 pandemic time.

Notes: