Clinical trial results:
The effect of tofacitinib on the activity of JAK-STAT pathways in patients with rheumatoid arthritis (RA)

Summary

EudraCT number	2017-002753-11
Trial protocol	FI
Global end of trial date	14 May 2020

Results information

Result version number	v1 (current)
This version publication date	18 May 2022
First version publication date	18 May 2022

Trial information

Trial identification

Sponsor protocol code	TofaSTAT17

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Tampere University Hospital
Sponsor organisation address	PO Box 2000, Tampere, Finland, 33521
Public contact	Centre for Rheumatology, Tampere University Hospital, pia.isomaki@tuni.fi
Scientific contact	Centre for Rheumatology, Tampere University Hospital, pia.isomaki@tuni.fi

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 January 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 May 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Which JAK-STAT pathways are significantly inhibited by tofacitinib in vivo?

Protection of trial subjects:

No specific measures

Background therapy:

Ongoing treatment with conventional systemic disease-modyfying anti-rheumatic drugs with or without prednisolone up to 10 mg per day

Evidence for comparator: -

Actual start date of recruitment	29 May 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	Finland: 18
Worldwide total number of subjects	18
EEA total number of subjects	18

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)	13
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Adult RA patients who are treated with tofacitinib and give their written informed consent, are recruited to the study. Patients need to have active disease (DAS28 > 3.2) despite treatment with methotrexate and other traditional disease-modifying anti-rheumatic drugs.

Pre-assignment

Screening details:

Inclusion criteria:
RA patient with active RA (DAS28 >3.2) despite treatment with methotrexate and other synthetic disease-modifying anti-rheumatic drugs
No prior biologic or JAK inhibitor treatment
Stable synthetic DMARD and prednisolone (0-10 mg/day) treatment allowed
Patient has no contra-indications to tofacitinib treatment

Period 1

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

Arms

Arm title	Tofacitinib

Arm description:

All patients were treated with tofacitinib 5 mg BID

Arm type	Experimental
Investigational medicinal product name	Tofacitinib citrate
Investigational medicinal product code	PR1
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Totacitinib 5 mg tablet twice daily

Number of subjects in period 1	Tofacitinib
Started	18
Completed	16
Not completed	2
Physician decision	2

Baseline characteristics

Reporting groups	
Reporting group title	Study treatment
Reporting group description:	
Includes the whole patient population	

Reporting group values	Study treatment	Total	
Number of subjects	18	18	
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			
arithmetic mean	58		
full range (min-max)	37 to 73	-	
Gender categorical Units: Subjects			
Female	13	13	
Male	5	5	

End points

End points reporting groups

Reporting group title	Tofacitinib

Reporting group description:

All patients were treated with tofacitinib 5 mg BID

Primary: DAS28 remission

End point title	DAS28 remission[1]

End point description:

The study protocol included aims of the study, but no primary or secondary endpoints were named for this trial in the study protocol. For the purpose of filling in this part of the report, a disease activity measure DAS28 remission is reported here as a primary endpoint.

End point type	Primary

End point timeframe:

DAS28 remission was determined at 3-mo visit

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: Please see additional information on the page. No primary end points were defined in the protocol of this study.

End point values	Tofacitinib			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: Number of subjects				
Remission	9			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Serious adverse events were reported from screening visit (0-3 mo before baseline visit) until a follow-up phone call which occurred 28 days after 3-mo visit

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.1

Frequency threshold for reporting non-serious adverse events: 0 %

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: For this phase IV study only serious adverse events were collected. Tofacitinib treatment was used as part of normal clinical care, and there was no control arm. Active treatment period was only 3 months. No serious adverse events were recorded during the study.

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