Clinical trial results:
T cells and TNF: The impact of TNF blockade on effector T cell populations in rheumatoid arthritis and other conditions treated with anti-TNF-alpha agents.

Summary

EudraCT number	2009-012424-87
Trial protocol	GB
Global end of trial date	21 December 2012

Results information

Result version number	v1 (current)
This version publication date	27 December 2019
First version publication date	27 December 2019

Trial information

Trial identification

Sponsor protocol code	2104091

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01060098
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Imperial College London
Sponsor organisation address	South Kensington Campus, London, United Kingdom, SW7 2AZ
Public contact	Dr Sonya Abraham, Imperial College London, +44 (0)20 3313 4114, s.abraham@imperial.ac.uk
Scientific contact	Dr Sonya Abraham, Imperial College London, +44 (0)20 3313 4114, s.abraham@imperial.ac.uk

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	02 December 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 December 2012
Global end of trial reached?	Yes
Global end of trial date	21 December 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of our research is to determine the effect of anti-TNF-alpha treatment on the levels of a cell type of the immune system, called Th17 cells and their product, IL-17 in blood samples and joint biopsies from patients with rheumatoid arthritis at different time points during treatment and how these changes correlate with parameters of systemic and local disease activity.

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 April 2010
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	United Kingdom: 48
Worldwide total number of subjects	48
EEA total number of subjects	48

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)	48
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited from Imperial College Healthcare NHS Trust clinics.

Pre-assignment

Screening details:

48 participants were eligible

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Rheumatoid arthritis

Arm description:

Participants diagnosed with Rheumatoid arthritis

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

Dosage and administration details:

50 mg

Arm title	Ankylosing spondylitis

Arm description:

Participants diagnosed with Ankylosing spondylitis

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

Dosage and administration details:

50 mg

Arm title	Psoriatic arthritis

Arm description:

Participants diagnosed with

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

Dosage and administration details:

50 mg

Number of subjects in period 1	Rheumatoid arthritis	Ankylosing spondylitis	Psoriatic arthritis
Started	25	15	8
Completed	25	15	8

Baseline characteristics

Reporting groups	
Reporting group title	Rheumatoid arthritis
Reporting group description:	
Participants diagnosed with Rheumatoid arthritis	
Reporting group title	Ankylosing spondylitis
Reporting group description:	
Participants diagnosed with Ankylosing spondylitis	
Reporting group title	Psoriatic arthritis
Reporting group description:	
Participants diagnosed with	

Reporting group values	Rheumatoid arthritis	Ankylosing spondylitis	Psoriatic arthritis
Number of subjects	25	15	8
Age categorical Units: Subjects			
Adults (18-64 years)	25	15	8
From 65-84 years	0	0	0
Age continuous Units: years			
arithmetic mean	57.4	36.4	50.9
standard deviation	± 11.7	± 11.8	± 8.4
Gender categorical Units: Subjects			
Female	18	3	5
Male	7	12	3

Reporting group values	Total		
Number of subjects	48		
Age categorical Units: Subjects			
Adults (18-64 years)	48		
From 65-84 years	0		
Age continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	26		
Male	22		

End points

End points reporting groups

Reporting group title	Rheumatoid arthritis
Reporting group description: Participants diagnosed with Rheumatoid arthritis	
Reporting group title	Ankylosing spondylitis
Reporting group description: Participants diagnosed with Ankylosing spondylitis	
Reporting group title	Psoriatic arthritis
Reporting group description: Participants diagnosed with	
Subject analysis set title	Baseline Rheumatoid arthritis
Subject analysis set type	Sub-group analysis
Subject analysis set description: Baseline of the Rheumatic arthritis participants	
Subject analysis set title	Baseline ankylosing spondylitis
Subject analysis set type	Sub-group analysis
Subject analysis set description: Baseline of the Ankylosing spondylitis participants	
Subject analysis set title	Baseline Psoriatic arthritis
Subject analysis set type	Sub-group analysis
Subject analysis set description: Baseline of Psoriatic arthritis participants	

Primary: Measurement of Effector T Helper Type 17 Cells in Peripheral Blood

End point title	Measurement of Effector T Helper Type 17 Cells in Peripheral Blood
End point description: The frequency of circulating Th17 cells was determined by IL17 enzyme-linked immunospot assay (Elispot) and flow cytometry (fluorescence-activated cell sorting (FACS)).	
End point type	Primary
End point timeframe: 0 and 12 weeks	

End point values	Rheumatoid arthritis	Ankylosing spondylitis	Psoriatic arthritis	Baseline Rheumatoid arthritis
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	25	15	8	25
Units: spSCF/10^6				
arithmetic mean (standard error)	759.8 (± 510)	651 (± 532)	609 (± 373)	466.4 (± 277)

End point values	Baseline ankylosing spondylitis	Baseline Psoriatic arthritis		

Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	15	8		
Units: spSCF/10^6				
arithmetic mean (standard error)	432 (± 474)	450 (± 276)		

Statistical analyses

Statistical analysis title	Rheumatoid Arthritis
Comparison groups	Rheumatoid arthritis v Baseline Rheumatoid arthritis
Number of subjects included in analysis	50
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	Ankylosing Spondylitis
Comparison groups	Ankylosing spondylitis v Baseline ankylosing spondylitis
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.04
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	Psoriatic Arthritis
Comparison groups	Psoriatic arthritis v Baseline Psoriatic arthritis
Number of subjects included in analysis	16
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.48
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 12 weeks	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	10

Reporting groups	
Reporting group title	Rheumatoid arthritis
Reporting group description: Participants diagnosed with Rheumatoid arthritis	
Reporting group title	Ankylosing spondylitis
Reporting group description: Participants diagnosed with Ankylosing spondylitis	
Reporting group title	Psoriatic arthritis
Reporting group description: Participants diagnosed with	

Serious adverse events	Rheumatoid arthritis	Ankylosing spondylitis	Psoriatic arthritis
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 25 (0.00%)	0 / 15 (0.00%)	0 / 8 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

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

Non-serious adverse events	Rheumatoid arthritis	Ankylosing spondylitis	Psoriatic arthritis
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 25 (0.00%)	0 / 15 (0.00%)	0 / 8 (0.00%)

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: No adverse events reported

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/25766640