Clinical trial results:
Evaluation of clinical value of a standardized protocol for dose reduction in patients with axial Spondyloarthritis and persistent clinical remission with anti-TNF therapy: Open-label, controlled, randomized, multicenter trial.

Summary

EudraCT number	2011-005871-18
Trial protocol	ES
Global end of trial date	10 June 2015

Results information

Result version number	v1 (current)
This version publication date	15 March 2022
First version publication date	15 March 2022
Summary attachment (see zip file)	Arthritis Research & Therapy doi.org/10.1186/s13075-018-1772-z (2019 REDES Arthritis research.pdf)

Trial information

Trial identification

Sponsor protocol code	REDES-TNF/2012

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	SEFC
Sponsor organisation address	C/Santa Isabel 51, Madrid, Spain, 28012
Public contact	CRISTINA AVENDAÑO-SOLÁ, CLINICAL PHARMACOLOGY DEPARTMENT- UNIVERSITARY HOSPITAL "PUERTA DE HIERRO", 34 911916479, cavendano.hpth@salud.madrid.org
Scientific contact	CRISTINA AVENDAÑO-SOLÁ, CLINICAL PHARMACOLOGY DEPARTMENT- UNIVERSITARY HOSPITAL "PUERTA DE HIERRO", 34 911916479, cavendano.hpth@salud.madrid.org

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	10 June 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 June 2015
Global end of trial reached?	Yes
Global end of trial date	10 June 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that patients with espondilartritis in remission under antiTNF therapy can maintain the remission with a maintenance dose inferior to the currently recommended dose schedule

Protection of trial subjects:

selection criteria

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 March 2012
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	Spain: 126
Worldwide total number of subjects	126
EEA total number of subjects	126

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)	126
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Diagnosis ofxSpA according to the ASAS classification criteria on treatment with the recommended doses of commercially available TNFi (infliximab, adalimumab, etanercept or golimumab) and in sustained clinical remission defined as Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)≤2, no clinically active arthritis

Period 1

Period 1 title	baseline
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Dose reduction

Arm description:

Reduced dose of TNF inhibitor according to protocol

Arm type	Experimental
Investigational medicinal product name	TNF Inhibitor
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled injector
Routes of administration	Subcutaneous use

Dosage and administration details:

reduced dose according to protocol

Arm title	control

Arm description:

full recommended TNFi dose

Arm type	Active comparator
Investigational medicinal product name	TNF Inhibitor
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled injector
Routes of administration	Subcutaneous use

Dosage and administration details:

According to approved SmPC

Number of subjects in period 1	Dose reduction	control
Started	63	63
Completed	63	63

Period 2	
Period 2 title	overall trial
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	Yes
Arm title	Dose reduction

Arm description:
Reduced dose of TNF inhibitor according to protocol

Arm type	Experimental
Investigational medicinal product name	TNF Inhibitor
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled injector
Routes of administration	Subcutaneous use

Dosage and administration details:
reduced dose according to protocol

Arm title	control

Arm description:
full recommended TNFi dose

Arm type	Active comparator
Investigational medicinal product name	TNF Inhibitor
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled injector
Routes of administration	Subcutaneous use

Dosage and administration details:
According to approved SmPC

Number of subjects in period 2	Dose reduction	control
Started	63	63
Completed	60	60
Not completed	3	3
not received allocated treatment	2	-
Lost to follow-up	1	2
not received medication	-	1

Baseline characteristics

End points

End points reporting groups

Reporting group title	Dose reduction
Reporting group description: Reduced dose of TNF inhibitor according to protocol	
Reporting group title	control
Reporting group description: full recommended TNFi dose	
Reporting group title	Dose reduction
Reporting group description: Reduced dose of TNF inhibitor according to protocol	
Reporting group title	control
Reporting group description: full recommended TNFi dose	

Primary: percentage of patients with Low Disease Activity

End point title	percentage of patients with Low Disease Activity[1]
End point description: percentage of patients with Low Disease Activity (BASDAI score<4, plus physician global assessment < 4, patient global assessment <4 and nocturnal axial pain <4 as assessed on a 0–10 visual analogue scale (VAS)) at one year	
End point type	Primary
End point timeframe: one year	

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 the published paper

End point values	Dose reduction	control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58	55		
Units: number of patients	58	55		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 3 years	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	17

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

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: Please, see the published paper

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/30621746