Clinical trial results:
The role of inflammatory biomarkers in pathophysiology of cardiovascular dysfunction in systemic inflammatory conditions- Part II

Summary

EudraCT number	2007-005464-26
Trial protocol	GB
Global end of trial date	30 April 2014

Results information

Result version number	v1 (current)
This version publication date	26 April 2019
First version publication date	26 April 2019
Summary attachment (see zip file)	FINAL STUDY REPORT (Puntmann2011_Article_UnravellingThePhenotypeOfCardi.pdf)

Trial information

Trial identification

Sponsor protocol code	RECrefno07/H0707/114

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	King's College London
Sponsor organisation address	The Strand, London, United Kingdom, WC2R 2LS
Public contact	Dr Valentina Puntmann, Kings College London, 0044 0207188 7242, v.puntmann@kcl.ac.uk
Scientific contact	Dr Valentina Puntmann, Kings College London, 0044 0207188 7242, v.puntmann@kcl.ac.uk
Sponsor organisation name	Guy's and St Thomas' NHS Foundation Trust
Sponsor organisation address	Great Maze Pond, London, United Kingdom, SE19RT
Public contact	Dr Valentina Puntmann, Guy's and St Thomas' NHS Foundation Trust, 0044 0207188 7242, v.puntmann@kcl.ac.uk
Scientific contact	Dr Valentina Puntmann, Guy's and St Thomas' NHS Foundation Trust, 0044 0207188 7242, v.puntmann@kcl.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	30 April 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 April 2014
Global end of trial reached?	Yes
Global end of trial date	30 April 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate TNF-alpha inhibitors altering cardiovascular function in patients with systemic inflammatory conditions (FMD, LV mass/LV volumes)

Protection of trial subjects:

Patients will be recruited from the respective speciality clinics (rheumatology, gastroenterology), only after clinical diagnoses have been established and the clinical decision on eligibility for anti-TNF therapy has been reached independently by the clinical team in
charge of the patient. Clinical decision making will be in line with the recommendations of the NICE guidelines and eligibility specifications outlined in SmPCs of the respective anti-TNF therapies (infliximab, etanercept and adalimumab). This also includes the concomitant
medication, such as the use of methotrexate in patients with rheumatoid arthritis.
Only adult patients were recruited. Women of childbearing potential needed to provide a negative pregnancy test prior to study entry.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 2008
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: 14
Worldwide total number of subjects	14
EEA total number of subjects	14

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)	14
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients will be recruited from the speciality clinics (rheumatology), only after clinical diagnoses have been established and the clinical decision on eligibility for anti-TNF therapy has been reached independently by the clinical team in charge of the patient.

Pre-assignment

Screening details:

Inclusion criteria in clinical trial: Male and female subjects over 18 years of age. Systemic inflammatory conditions (Rheumatoid arthritis) - diagnosis established independently by the clinical team Eligibility for anti-TNF-α therapy – decision to start treatment will be reached independently by the clinical team.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Remicade

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Remicade
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Total 3mg/Kg

Arm title	Enbrel

Arm description: -

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

Dosage and administration details:

50 mg milligram(s)

Number of subjects in period 1	Remicade	Enbrel
Started	9	5
Completed	9	5

Baseline characteristics

Reporting groups	
Reporting group title	Remicade
Reporting group description: -	
Reporting group title	Enbrel
Reporting group description: -	

Reporting group values	Remicade	Enbrel	Total
Number of subjects	9	5	14
Age categorical Units: Subjects			
Adults (18-64 years)	9	5	14
Gender categorical Units: Subjects			
Female	4	5	9
Male	5	0	5

End points

End points reporting groups

Reporting group title	Remicade
Reporting group description: -	
Reporting group title	Enbrel
Reporting group description: -	

Primary: Primary Endpoint

End point title	Primary Endpoint[1]

End point description:

1. Aortic distensibility and stiffness studies (PWV and AD)
2. Myocardial function (LV mass, LV volumes)

End point type	Primary

End point timeframe:

From baseline to 18 months post initiation of anti-TNF therapy

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 final study report

End point values	Remicade	Enbrel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	5		
Units: Subject having PWV and AD	9	5		

Attachments (see zip file)	Trial

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

From consent to 18 months after anti-TNF therapy was initiated.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

Reporting group title	Remicade
Reporting group description: -	
Reporting group title	Enbrel
Reporting group description: -	

Serious adverse events	Remicade	Enbrel	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 9 (0.00%)	0 / 5 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Remicade	Enbrel	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 9 (0.00%)	0 / 5 (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 AEs were reported during the trial

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 October 2009	Amendment made when study was being conducted by previous sponsor.
15 March 2012	Change of sponsor from Imperial to King's College London and Guy's and St. Thomas' NHS Foundation Trust
24 May 2012	The addition of IMP Certolizumab pegol (Cimzia) as this has become the first line agent in treating rheumatoid patients at St. Thomas' Hospital. Addition of "demyelinating disease" to the listed exclusion criteria, this is listed as a precaution for use in the Cimzia SmPC dated 14/01/2013.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported