Clinical trial results:
ARNS HC 21 VASCU IL-2, evaluation of the cellular immune response, clinical efficacy and tolerance after IL-2 therapy in HCV-related Vasculitis patients, resistant to conventional therapy

Summary

EudraCT number	2006-004039-31
Trial protocol	FR
Global end of trial date	16 September 2010

Results information

Result version number	v1 (current)
This version publication date	08 March 2024
First version publication date	08 March 2024

Trial information

Trial identification

Sponsor protocol code	ANRS HC 21 VASCU IL-2

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00574652
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Inserm-ANRS
Sponsor organisation address	101 rue de Tolbiac, Paris, France, 75013
Public contact	Pr. Pactrice CACOUB, Hôpital de la Pitié, +33 1 42 17 80 09, patrice.cacoub@aphp.fr
Scientific contact	Pr. Pactrice CACOUB, Hôpital de la Pitié, +33 1 42 17 80 09, patrice.cacoub@aphp.fr

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	16 September 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 September 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial is to evaluate the cellular immune response after IL-2 therapy in HCV-MC Vasculitis patients, resistant to conventional therapy.

Protection of trial subjects:

This study was conducted in accordance with the updated Declaration of Helsinki, in compliance with the approved protocol and its amendments, the International Council for Harmonisation guideline for Good Clinical Practice (ICH GCP), and French regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 March 2008
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	7 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	7
From 65 to 84 years	3

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Main criteria:
Inclusion: at least 18 years old, Caucasian origin, chronic active HCV infection, patients with cryoglobulinemia vasculitis resistant to conventional therapy.
Non-inclusion: HBs Ag+ and/or HBV+ PCR, HIV+ serology, Cirrhosis Child B or C.

Period 1

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

Arms

Arm title	Vascu IL-2 arm

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Interleukine-2
Investigational medicinal product code	
Other name	IL-2, Proleukine
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

IL-2 will be injected subcutaneaously from D1 to D5 every 3 weeks over 4 consecutive cycles (W1, W3, W6 and W9).
W1: dose of 1.5M IU/day by injection of 0.25mL.
W3, W6 and W9: 3M IU/day by injection of 0.5mL.

Number of subjects in period 1	Vascu IL-2 arm
Started	10
Completed	10

Baseline characteristics

Reporting groups	
Reporting group title	Vascu IL-2 arm

Reporting group description: -

Reporting group values	Vascu IL-2 arm	Total	
Number of subjects	10	10	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	7	7	
From 65-84 years	3	3	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	5	5	
Male	5	5	

End points

End points reporting groups

Reporting group title	Vascu IL-2 arm

Reporting group description: -

Primary: Regulatory T cell

End point title	Regulatory T cell[1]

End point description:

Follow-up of Treg and of HCV cellular immune response before, during and after IL-2 therapy.

End point type	Primary

End point timeframe:

Difference between W9 and D0 and post IL-2 treatment.

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: This endpoint concerns a single arm, adding statistical analyses create errors.

End point values	Vascu IL-2 arm			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Difference of percentage				
arithmetic mean (standard deviation)	8.1 (± 5.8)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Participants reported adverse events during the entire trial.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	Vascu IL-2 arm

Reporting group description: -

Serious adverse events	Vascu IL-2 arm		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 10 (50.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphoproliferative disorder			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cryoglobulinaemia			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Vasculitis			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Hospitalisation			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Blood and lymphatic system disorders			
Pancytopenia			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Leukopenia			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Injection site inflammation			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Cellulitis			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Psychiatric decompensation			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Sinusitis			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Tooth abscess			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Vascu IL-2 arm		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	2		
Hypotension			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Thrombocytopenia			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	5 / 10 (50.00%)		
occurrences (all)	9		
Chest pain			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Injection site pain			
subjects affected / exposed	4 / 10 (40.00%)		
occurrences (all)	8		
Injection site reaction			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		

Pyrexia subjects affected / exposed occurrences (all)	5 / 10 (50.00%) 7		
Eye disorders Visual impairment subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Musculoskeletal and connective tissue disorders Myalgia subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 December 2009	The substantial modifications included in the amendment 1 of the protocol are: - the extension of the inclusion period for an additional 6 months - the inclusion of 10 patients instead of the 15 initially planned.

Notes:

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/22129253