Clinical trial results:
A protocol based treatment for early and severe systemic sclerosis with (anti-CD-20) rituximab

Summary

EudraCT number	2006-003836-31
Trial protocol	BE
Global end of trial date	16 January 2020

Results information

Result version number	v1 (current)
This version publication date	04 December 2024
First version publication date	04 December 2024
Summary attachment (see zip file)	Publication (Publicatie.pdf)

Trial information

Trial identification

Sponsor protocol code	AGO/2006/007

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	University Hospital Ghent
Sponsor organisation address	C. Heymanslaan, Ghent, Belgium, 9000
Public contact	University Hospital Ghent, University Hospital Ghent, 32 093320530, hiruz.ctu@uzgent.be
Scientific contact	University Hospital Ghent, University Hospital Ghent, 32 093320530, hiruz.ctu@uzgent.be

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 January 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 January 2020
Global end of trial reached?	Yes
Global end of trial date	16 January 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy and the toxicity of anti-CD-20 in patients with early and severe systemic sclerosis

Protection of trial subjects:

See attachment

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 November 2006
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	Belgium: 8
Worldwide total number of subjects	8
EEA total number of subjects	8

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)	8
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

See attachment

Pre-assignment

Screening details:

See Attachement

Period 1

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

Arms

Arm title	General

Arm description:

See attachment

Arm type	Active comparator
Investigational medicinal product name	rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

See Attachment

Number of subjects in period 1	General
Started	8
Completed	8

Baseline characteristics

End points

End points reporting groups

Reporting group title	General
Reporting group description:	
See attachment	

Primary: Primary

End point title	Primary[1]
End point description:	
End point type	Primary
End point timeframe:	
See attachement	

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: See Attachment

End point values	General			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: See attachment				
number (not applicable)	8			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
During the study	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

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: See Attachment

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