



Clinical trial results:

A multicenter, randomized, placebo-controlled, double-blind proof of concept study to evaluate the efficacy and safety of the human normal immunoglobulin Intratect® 5% for intravenous use as adjuvant therapy in patients with Pemphigus Vulgaris

Summary

EudraCT number	2013-000211-24
Trial protocol	DE
Global end of trial date	10 December 2014

Results information

Result version number	v1 (current)
This version publication date	14 March 2020
First version publication date	14 March 2020
Summary attachment (see zip file)	Statement IMAT-PV 2013-000211-24 (Statement_IMAT-PV_2013-000211-24.pdf)

Trial information

Trial identification

Sponsor protocol code	IMAT-PV
-----------------------	---------

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Ruprecht-Karls-University Heidelberg, Medical Faculty represented by Universitätsklinikum Heidelberg and Acting Business Director
Sponsor organisation address	Im Neuenheimer Feld 672, Heidelberg, Germany, 69120
Public contact	Department of Dermatology, University of Heidelberg, +49 6221 5637143, Eva.Hadaschik@med.uni-heidelberg.de
Scientific contact	Department of Dermatology, University of Heidelberg, +49 6221 5637143, Eva.Hadaschik@med.uni-heidelberg.de

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 December 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	10 December 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The proportion of patients suffering relapse (Relapse rate) during IVIG or placebo treatment within 12 months

Relapse: The appearance of ≥ 3 new lesions a month that do not heal spontaneously within 1 week, or by the extension of established lesions in a patient who has achieved disease control.

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 June 2013
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	Germany: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	0
From 65 to 84 years	99999
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

Pre-assignment

Screening details:

N/A

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

N/A

Arms

Arm title	Intratect
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Intratect 5%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

N/A

Number of subjects in period 1	Intratect
Started	99999
Completed	99999

Baseline characteristics

End points

End points reporting groups

Reporting group title	Intratect
Reporting group description: -	

Primary: The proportion of patients suffering relapse (Relapse rate) during IVIG or placebo treatment within 12 months

End point title	The proportion of patients suffering relapse (Relapse rate) during IVIG or placebo treatment within 12 months ^[1]
-----------------	--

End point description:

End point type	Primary
----------------	---------

End point timeframe:

N/A

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: Justification: 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.
No statistical analyses for this end point.

End point values	Intratect			
Subject group type	Reporting group			
Number of subjects analysed	99999 ^[2]			
Units: N/A	99999			

Notes:

[2] - No subjects were enrolled in the trial hence results are not available.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

All adverse events occurring during the course of the clinical trial were to be collected.

Adverse event reporting additional description:

N/A

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	16.0
--------------------	------

Reporting groups

Reporting group title	Intratect
-----------------------	-----------

Reporting group description: -

Serious adverse events	Intratect		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Intratect		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 99999 (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 subjects were enrolled in the trial hence results are not available.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 October 2013	Clarifications and responses to subsequent demands of the Ethics Committee

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

No subjects were enrolled in the Trial hence results are not available.

Notes: