Clinical trial results:
A Phase II trial of Ofatumumab in patients with lymphoma of the of the mucosa associated lymphoid tissue (MALT-Lymphoma)

Summary

EudraCT number	2012-005223-32
Trial protocol	AT
Global end of trial date	19 September 2016

Results information

Result version number	v1 (current)
This version publication date	16 July 2021
First version publication date	16 July 2021

Trial information

Trial identification

Sponsor protocol code	O-Ma 1

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medizinische Universität Wien
Sponsor organisation address	Spitalgasse 23, Vienna, Austria, 1090
Public contact	Marika Rosner, Medizinische Universität Wien, 0043 14040044450, marika.rosner@meduniwien.ac.at
Scientific contact	Ao. Prof. Dr. Markus Raderer, Medizinische Universität Wien, 0043 14040044450, markus.raderer@meduniwien.ac.at

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	29 February 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 February 2016
Global end of trial reached?	Yes
Global end of trial date	19 September 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Efficacy of IMP in patients with MALT-Lymphoma

Protection of trial subjects:

CT thorax and abdomen and endoscopy at screening, week 12, 24 and 42

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 September 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	Austria: 16
Worldwide total number of subjects	16
EEA total number of subjects	16

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)	6
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment was done through the outpatient clinic unit

Pre-assignment

Screening details:

The screening was based on the screening criteria

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Ofatumumab

Arm description:

Single arm study, all patients receive ofatumumab

Arm type	Experimental
Investigational medicinal product name	Ofatumumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1000 mg i.v weekly for 4 weeks followed by 4 cycles every 2 month

Number of subjects in period 1	Ofatumumab
Started	16
Completed	16

Baseline characteristics

Reporting groups

Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	16	16	
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)	6	6	
From 65-84 years	10	10	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	9	9	
Male	7	7	

Subject analysis sets

Subject analysis set title	Ofatumumab
Subject analysis set type	Per protocol

Subject analysis set description:

Single arm study, all patients receive ofatumumab

Reporting group values	Ofatumumab		
Number of subjects	16		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	6		
From 65-84 years	10		
85 years and over	0		

Gender categorical Units: Subjects			
Female	9		
Male	7		

End points

End points reporting groups

Reporting group title	Ofatumumab
Reporting group description: Single arm study, all patients receive ofatumumab	
Subject analysis set title	Ofatumumab
Subject analysis set type	Per protocol
Subject analysis set description: Single arm study, all patients receive ofatumumab	

Primary: Objective responses rate

End point title	Objective responses rate
End point description:	
End point type	Primary
End point timeframe: after 24 weeks	

End point values	Ofatumumab	Ofatumumab		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	16	16		
Units: 15				
number (not applicable)	15	15		

Statistical analyses

Statistical analysis title	Objective responses rate
Comparison groups	Ofatumumab v Ofatumumab
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	< 0.4
Method	Simon`s two stage design
Parameter estimate	descreptive
Confidence interval	
level	95 %
Variability estimate	Standard deviation

Notes:

[1] - per protocol

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Time from signing informed consent throught the end of FU period	
Assessment type	Systematic
Dictionary used	
Dictionary name	CI CTCAE
Dictionary version	V3.0
Reporting groups	
Reporting group title	specific and unspecific Adverse Events
Reporting group description:	
Toxicities were mainly mild	

Serious adverse events	specific and unspecific Adverse Events		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 14 (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	specific and unspecific Adverse Events		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 14 (100.00%)		
Product issues			
infusions reactions	Additional description: reactions due to ofatumumab		
subjects affected / exposed	14 / 14 (100.00%)		
occurrences (all)	14		

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/28695630