Clinical trial results:
A PHASE II TRIAL OF LONG-TERM TREATMENT WITH AZITHROMYCIN IN PATIENTS WITH LYMPHOMA OF THE MUCOSA ASSOCIATED LYMPHOID TISSUE (MALT) LYMPHOMA

Summary

EudraCT number	2016-001521-13
Trial protocol	AT
Global end of trial date	11 June 2019

Results information

Result version number	v1 (current)
This version publication date	26 February 2021
First version publication date	26 February 2021

Trial information

Trial identification

Sponsor protocol code	MALT-A1

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	MedUniWien
Sponsor organisation address	Spitalgasse 23, Wien, Austria, 1090
Public contact	Marika Rosner, MedUniWien, +43 14040044450, marika.rosner@meduniwien.ac.at
Scientific contact	Markus Raderer, MedUniWien, +43 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	14 June 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 June 2018
Global end of trial reached?	Yes
Global end of trial date	11 June 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the capacity of azithromycin to induce objective responses in patients with MALT lymphoma, either untreated or at relapse after surgery, radiation and chemotherapy. In addition, also patients with disease refractory to HP-eradication after a minimum follow-up of 12 months will be enrolled. Patients with gastric MALT lymphoma and no evidence of HP-infection (as judged by histology and ultimately serology) may be enrolled immediately.

Protection of trial subjects:

no protection needed for this IMP

Background therapy:

no background therapy needed for this IMP

Evidence for comparator: -

Actual start date of recruitment	13 June 2016
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	9
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

recruitment was done through the outpatient clinic unit

Pre-assignment

Screening details:

The screening was done on the basis of 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	Azithromycin

Arm description:

Single arm study, all patients receive azithromycin

Arm type	Experimental
Investigational medicinal product name	azithromycin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

1500mg azithromycin once a week

Number of subjects in period 1	Azithromycin
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	9	9	
85 years and over	1	1	
Gender categorical Units: Subjects			
Female	10	10	
Male	6	6	

Subject analysis sets	
Subject analysis set title	objective response rate
Subject analysis set type	Per protocol

Subject analysis set description:
sinons rule set

Reporting group values	objective response rate		
Number of subjects	16		
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)	6		
From 65-84 years	9		
85 years and over	1		

Gender categorical Units: Subjects			
Female	10		
Male	6		

End points

End points reporting groups

Reporting group title	Azithromycin
Reporting group description: Single arm study, all patients receive azithromycin	
Subject analysis set title	objective response rate
Subject analysis set type	Per protocol
Subject analysis set description: sinons rule set	

Primary: Rate of objective responses

End point title	Rate of objective responses
End point description:	
End point type	Primary
End point timeframe: after 24 weeks	

End point values	Azithromycin	objective response rate		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	16	16		
Units: numbers	16	16		

Statistical analyses

Statistical analysis title	Objective response rate
Comparison groups	Azithromycin v objective response rate
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

Notes:
[1] - descreptive

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Time of signing the informed consent through to the end of the designated follow-up period	
Assessment type	Systematic
Dictionary used	
Dictionary name	NCI CTCAE
Dictionary version	3.0
Reporting groups	
Reporting group title	unspecific Adverse Events
Reporting group description: Toxicities were mainly mild and mostly unspecific	

Serious adverse events	unspecific Adverse Events		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 16 (12.50%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
General disorders and administration site conditions			
General disorder due to MALT lymphoma	Additional description: General disorder due to MALT lymphoma nrelated to the IMP.		
subjects affected / exposed	2 / 16 (12.50%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	unspecific Adverse Events		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 16 (81.25%)		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	3 / 16 (18.75%)		
occurrences (all)	3		
Chills			

subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		
Headache			
subjects affected / exposed	3 / 16 (18.75%)		
occurrences (all)	3		
Vertigo			
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		
Gastrointestinal disorders			
Nausea/Vomiting			
subjects affected / exposed	13 / 16 (81.25%)		
occurrences (all)	13		
gastrointestinal complaints	Additional description: gastrointestinal complaints (including flatulence, bloating, and cramps, dyspepsia)		
subjects affected / exposed	12 / 16 (75.00%)		
occurrences (all)	12		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Joint pain			
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		

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/30153341