Clinical trial results:
Treatment of chronic lymphocytic leukemia with the use of an antiviral compound - a proof of principle study

Summary

EudraCT number	2010-021786-78
Trial protocol	AT
Global end of trial date	18 April 2015

Results information

Result version number	v1 (current)
This version publication date	19 March 2021
First version publication date	19 March 2021

Trial information

Trial identification

Sponsor protocol code	V1_30.4.2010

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of VIenna
Sponsor organisation address	Währinger Gürtel 18-20, Vienna, Austria, 1090
Public contact	Department of Medicine I, Medical University of Vienna, 0043 14040044400, christoph.steininger@meduniwien.ac.at
Scientific contact	Department of Medicine I, Medical University of Vienna, +43 14040044400, christoph.steininger@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	26 February 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 February 2015
Global end of trial reached?	Yes
Global end of trial date	18 April 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Evaluation of the response of CLL patients to a three months course of antiviral prophylaxis as measured by the kinetics of the absolute lymphocyte count of CLL patients

Protection of trial subjects:

Detailled assessment of history of allergic reactions, contraindications and risk for adverse reactions to study medication, patient health insurance and external monitoring was done to minimize potential adverse events

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 July 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 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)	3
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Our institution (Department of Medicine I, Medical University of Vienna) is a university-affiliated, tertiary care centre. The Department of Hematology is internationally renowned for its expertise in neoplasias of the blood and lymphatic tissue. A total of 8 patients was recruited.

Pre-assignment

Screening details:

Signed informed consent was obtained from all patients prior to any specific procedure. The investigator confirmed eligibility of the patient according to the inclusion and exclusion criteria. Screening and baseline visit occurred within 12 weeks of the first IMP administration.

Period 1

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

Arms

Arm title	Treatment

Arm description:

Each patient will participate in a screening period, a baseline visit, a treatment phase of approximately 3 months within at least 3 visits at site and a follow-up period of 9 months including 3 follow up visits, every 3 months, at site. Valganciclovir (VGCV) at a dose of 900 mg (2x 450mg tablets) once daily (dosage will be adapted in patients with renal insufficiency) will be used as antiviral prophylaxis for 3 months.

Arm type	Proof-of-principle
Investigational medicinal product name	Valganciclovir
Investigational medicinal product code	n/a
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Valganciclovir (VGCV) at a dose of 900 mg (2x 450mg tablets) once daily (dosage was adapted in patients with renal insufficiency) was used as antiviral prophylaxis for 3 months.

Number of subjects in period 1	Treatment
Started	8
Completed	7
Not completed	1
Adverse event, non-fatal	1

Baseline characteristics

Reporting groups

Reporting group title	Baseline

Reporting group description: -

Reporting group values	Baseline	Total	
Number of subjects	8	8	
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)	3	3	
From 65-84 years	5	5	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	2	2	
Male	6	6	

Subject analysis sets

Subject analysis set title	Assessment of treatment
Subject analysis set type	Full analysis

Subject analysis set description:

kinetics of the total lymphocyte count before, during, and up to 9 months after antiviral therapy

Reporting group values	Assessment of treatment		
Number of subjects	7		
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)	3		
From 65-84 years	5		
85 years and over			

Gender categorical Units: Subjects			
Female	2		
Male	5		

End points

End points reporting groups

Reporting group title	Treatment

Reporting group description:

Each patient will participate in a screening period, a baseline visit, a treatment phase of approximately 3 months within at least 3 visits at site and a follow-up period of 9 months including 3 follow up visits, every 3 months, at site. Valganciclovir (VGCV) at a dose of 900 mg (2x 450mg tablets) once daily (dosage will be adapted in patients with renal insufficiency) will be used as antiviral prophylaxis for 3 months.

Subject analysis set title	Assessment of treatment
Subject analysis set type	Full analysis

Subject analysis set description:

kinetics of the total lymphocyte count before, during, and up to 9 months after antiviral therapy

Primary: Lymphocyte count at 12 months

End point title	Lymphocyte count at 12 months

End point description:

End point type	Primary

End point timeframe:

Lymphocyte count at 12 months

End point values	Treatment	Assessment of treatment		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	8	7		
Units: Number per liter				
number (not applicable)	8	7		

Statistical analyses

Statistical analysis title	Change in lymphocyte count

Statistical analysis description:

Patients receiving antiviral therapy and harbouring CMV will benefit from treatment which should result in a reduction of lymphocyte counts due to newly formed lymphocytes undergoing normal apoptotic behaviour. Under this assumption during 3 months of treatment the reduction of lymphocyte counts should amount to about 5-10% in CMV positive patients. Assuming a reduction of this magnitude will amount to a standardized effect size of about 0.3 and a correlation of 0.8 between log lymphocyte counts

Comparison groups	Treatment v Assessment of treatment
Number of subjects included in analysis	15
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 2-sided
Parameter estimate	n/a

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 12 months	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	23
Reporting groups	
Reporting group title	Treatment

Reporting group description: -

Serious adverse events	Treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (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	Treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 8 (12.50%)		
Musculoskeletal and connective tissue disorders			
Myalgia	Additional description: Mild myalgia		
subjects affected / exposed	1 / 8 (12.50%)		
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