



Clinical trial results: Studio PKCT - Pharmacokinetics of chemotherapy when given concurrently with antiretroviral (Protocol no. CSL01).

Summary

EudraCT number	2010-023749-30
Trial protocol	IT
Global end of trial date	

Results information

Result version number	v1 (current)
This version publication date	06 March 2020
First version publication date	06 March 2020
Summary attachment (see zip file)	Poster (Poster PKCT_20052014.ppt)

Trial information

Trial identification

Sponsor protocol code	PKCTnrCSL01
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Ospedale San Raffaele Srl
Sponsor organisation address	Via Stamira d'Ancona 20, Milan, Italy, 20127
Public contact	Ospedale San Raffaele Srl, Ospedale San Raffaele Srl, 0039 0226437934, carini.elisabetta@hsr.it
Scientific contact	Ospedale San Raffaele Srl, Ospedale San Raffaele Srl, 0039 0226433473, castagna.antonella1@hsr.it

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	Interim
Date of interim/final analysis	31 December 2012
Is this the analysis of the primary completion data?	No

Global end of trial reached?	No
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Notes:

General information about the trial

Main objective of the trial:

to study the pharmacokinetics of DX before and after the replacement of antiretroviral therapy that may alter the activity of the subunit CYP3A4 of the cytochrome p450 with raltegravir (drug that does not affect the activity of cytochrome p450).

Protection of trial subjects:

Helsinki Declaration, CEE Regulations, GCP for trials on medical products in the European Community, Italian ICH.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 November 2011
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	Italy: 3
Worldwide total number of subjects	3
EEA total number of subjects	3

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	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subject with HIV infection and diagnosis of HL and NHL treated with ABVD and R-CHOP respectively, doxorubicin PK on course of initial treatment with NNRTI or boosted PI and after switch to raltegravir including regimen.

Pre-assignment

Screening details:

Patients already on antiretroviral therapy and already being treated at our center, aged > 18 years and HD or NHL who require CT according to ABVD or (r) CHOP were enrolled.

Period 1

Period 1 title	ABVD or CHOP treatment+cART ongoing
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	ABVD or R-CHOP + ongoing cART
Arm description: -	
Arm type	prospective evaluation
Investigational medicinal product name	ABVD or R-CHOP + ongoing cART
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ABVD+EFV+TDF/FCT or
R-CHOP+DRV/R+TDF/FCT or
R-CHOP+LPV/R+3TC+DDI

Number of subjects in period 1	ABVD or R-CHOP + ongoing cART
Started	3
Completed	3

Period 2

Period 2 title	Raltegravir period
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	ABVD or R-CHOP + RAL + cART
Arm description: ABVD+RAL+TDF/FTC R-CHOP+RAL+TDF/FTC R-CHOP+RAL+3TC+DDI	
Arm type	Active comparator
Investigational medicinal product name	RALTEGRAVIR
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

RALTEGRAVIR 400 MG/bid STANDARD DOSAGE

Number of subjects in period 2	ABVD or R-CHOP + RAL + cART
Started	3
Completed	3

Baseline characteristics

Reporting groups

Reporting group title	ABVD or CHOP treatment+cART ongoing
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Reporting group description: -

Reporting group values	ABVD or CHOP treatment+cART ongoing	Total	
Number of subjects	3	3	
Age categorical			
Adult patients			
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	0	0	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	0	0	
Male	3	3	

Subject analysis sets

Subject analysis set title	Prospective evaluation per protocol
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Subject analysis set type	Per protocol
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Subject analysis set description:

Prospective evaluation on HIV-subjects treated with 2 NRTIs in association with boosted PI or NNRTI receiving R-CHOP or ABVD chemotherapy for NHL and HL.

Reporting group values	Prospective evaluation per protocol		
Number of subjects	3		
Age categorical			
Adult patients			
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)	3		
From 65-84 years	0		
85 years and over	0		
Gender categorical			
Units: Subjects			
Female			
Male			

End points

End points reporting groups

Reporting group title	ABVD or R-CHOP + ongoing cART
Reporting group description: -	
Reporting group title	ABVD or R-CHOP + RAL + cART
Reporting group description: ABVD+RAL+TDF/FTC R-CHOP+RAL+TDF/FTC R-CHOP+RAL+3TC+DDI	
Subject analysis set title	Prospective evaluation per protocol
Subject analysis set type	Per protocol
Subject analysis set description: Prospective evaluation on HIV-subjects treated with 2 NRTIs in association with boosted PI or NNRTI receiving R-CHOP or ABVD chemotherapy for NHL and HL.	

Primary: PK concentration of doxorubicine co-administered with antiretroviral therapy and DX PK after switch to Raltegravir

End point title	PK concentration of doxorubicine co-administered with antiretroviral therapy and DX PK after switch to Raltegravir
End point description: 11 timepoints of PK concentration at baseline (period 1) and 11 timepoints of PK concentration at period 2 (chemotherapy + raltegravir)	
End point type	Primary
End point timeframe: 11 timepoints of PK concentration at baseline (period 1) and 11 timepoints of PK concentration at period 2 (chemotherapy + raltegravir)	

End point values	ABVD or R-CHOP + ongoing cART	ABVD or R-CHOP + RAL + cART		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	3		
Units: pharmacokinetic	3	3		

Statistical analyses

Statistical analysis title	Per protocol
Statistical analysis description: per protocol	
Comparison groups	ABVD or R-CHOP + ongoing cART v ABVD or R-CHOP + RAL + cART

Number of subjects included in analysis	6
Analysis specification	Post-hoc
Analysis type	other ^[1]
P-value	= 0 ^[2]
Method	per protocol

Notes:

[1] - per protocol based on 3 subject completed

[2] - Analysis per protocol based on 3 subject completed

P-value is not applicable

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Until the end of the participation in the study (end of treatment with raltegravir)

Assessment type | Systematic

Dictionary used

Dictionary name | MedDRA

Dictionary version | 1

Reporting groups

Reporting group title | R-CHOP + ARV

Reporting group description:

R-CHOP + DRV/r+TDF/FTC (first cycle)

R-CHOP + RAL + TDF/FTC (second cycle)

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: None non serious Adverse Events were observed during the study

Serious adverse events	R-CHOP + ARV		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Immune system disorders			
Dead for progression of diseases			
subjects affected / exposed ^[2]	1 / 1 (100.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Notes:

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: 1 subject dead for progression of diseases

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	R-CHOP + ARV		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)		

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