Clinical trial results:
HIV Reservoir Dynamics After Switching To Dolutegravir in Patients on a PI/r Based Regimen. A Phase IV Open Randomized Trial

Summary

EudraCT number	2014-004331-39
Trial protocol	ES
Global end of trial date	29 June 2017

Results information

Result version number	v1 (current)
This version publication date	31 October 2021
First version publication date	31 October 2021

Trial information

Trial identification

Sponsor protocol code	INDOOR

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	VHIR
Sponsor organisation address	Passeig Vall Hebron 119-129, Barcelona, Spain, 08035
Public contact	Joaquin Lopez-Soriano, VHIR, 0034 934894779, joaquin.lopez.soriano@vhir.org
Scientific contact	Unitat de malalties infeccioses, Fundación Vall Hebron Institut de Recerca, 0034 934893000, mcrespo@vhebron.net

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 June 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 June 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the HIV reservoir dynamics after the change of IP / r by dolutegravir in HIV-1 infected patients that they maintain suppressed the viral load (HIV RNA <50 copies / ml) with AN ART 2 and 1 IP / r

Protection of trial subjects:

According to routine care practice and physician criteria, blood tests were performed every 3–6 months in these patients.
This study was conducted in accordance with local ethical and legal requirements. The study protocol was approved by each hospital's local ethics committee and the Spanish Agency for Medicines and Healthcare Products (AEMPS). The study was conducted according to the Good Clinical Practice Guidelines

Background therapy:

Antiretroviral treatment (ART) guidelines recommend the use of three active drugs to treat human immunodeficiency virus (HIV) infection in both treatment-naive and treatment-experienced patients. Nonstandard ARTs may include complex regimens that usually entail high pill burden and/or twice/day administration, and frequently recycled or partially active drugs

Evidence for comparator: -

Actual start date of recruitment	02 February 2015
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	Spain: 50
Worldwide total number of subjects	50
EEA total number of subjects	50

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)	50
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	50
Number of subjects completed	50

Period 1

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

Arms

Arm title	Switch to DTG+DRV/b

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Dolutegravir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Pillules
Routes of administration	Oral use

Dosage and administration details:

2-4 daily 10mg pills, orally

Number of subjects in period 1	Switch to DTG+DRV/b
Started	50
Completed	50

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	50	50	
Age categorical Units: Subjects			
Adults (18-64 years)	50	50	
Gender categorical Units: Subjects			
Female	18	18	
Male	32	32	

End points

End points reporting groups

Reporting group title	Switch to DTG+DRV/b

Reporting group description: -

Primary: DTG+ DRV/b effectiveness

End point title	DTG+ DRV/b effectiveness[1]

End point description:

The primary outcome was once/day DTG+ DRV/b effectiveness, defined as the percentage of patients with a VL of 50 copies/ml or lower at last follow-up visit

End point type	Primary

End point timeframe:

Last visit at end of study (17-28 months, median 25 months)

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: No statistics is given, since there are not arms nor control/placebo groups for comparison

End point values	Switch to DTG+DRV/b			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: percent				
number (not applicable)	50			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
End of study	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	14.1

Reporting groups	
Reporting group title	DTG switch

Reporting group description: -

Serious adverse events	DTG switch		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 50 (0.00%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	DTG switch		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 50 (4.00%)		
General disorders and administration site conditions			
Insomnia			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
Product issues			
Impaired adherence			
subjects affected / exposed	1 / 50 (2.00%)		
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

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

Mainly it is a small retrospective study without a control group, and thus confounding factors may interfere in the results

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/30723941