



## Clinical trial results:

### A study to assess the acceptability/swallowability of DRV-containing FDC tablets in HIV-1 infected adolescents, using matching placebo tablets

#### Summary

EudraCT number	2016-003016-12
Trial protocol	Outside EU/EEA
Global end of trial date	27 May 2017

#### Results information

Result version number	v1 (current)
This version publication date	21 March 2019
First version publication date	21 March 2019

#### Trial information

##### Trial identification

Sponsor protocol code	TMC114FD2HTX1003
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02993237
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	Janssen Research & Development LLC
Sponsor organisation address	Archimedesweg 29, Leiden, Netherlands, 2333CM
Public contact	Clinical Registry group, Janssen Research & Development LLC, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry group, Janssen Research & Development LLC, ClinicalTrialsEU@its.jnj.com

Notes:

#### Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-001280-PIP01-12, EMA-001825-PIP01-15
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?	Yes

Notes:

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**Results analysis stage**

Analysis stage	Final
Date of interim/final analysis	27 May 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 May 2017
Was the trial ended prematurely?	No

Notes:

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**General information about the trial**

Main objective of the trial:

The primary objective is to assess the acceptability of swallowing the Darunavir/cobicistat (DRV/COBI) and darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) fixed-dose combination (FDC) tablets, using matching placebo tablets, in a human immunodeficiency virus (HIV-1) infected adolescent subjects.

Protection of trial subjects:

Safety and tolerability was evaluated throughout the study from signing of the Informed Consent Form (ICF)/Assent Form onwards until the last study-related activity.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 January 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

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**Population of trial subjects****Subjects enrolled per country**

Country: Number of subjects enrolled	United States: 27
Worldwide total number of subjects	27
EEA total number of subjects	0

Notes:

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**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)	27
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

In total, 27 subjects were enrolled in the study and all completed the study as planned, by taking the reference placebo tablet, followed by the DRV/COBI placebo or D/C/F/TAF FDC placebo tablet.

### Period 1

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

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	D/C/F/TAF FDC placebo followed by DRV/COBI FDC placebo

Arm description:

Subjects received 1 placebo tablet matching the D/C/F/TAF 800/150/200/10 mg FDC (Intake 1) and 1 placebo tablet matching the DRV/COBI FDC (Intake 2) on Day 1. Both the intakes were separated by at least 30 minutes.

Arm type	Experimental
Investigational medicinal product name	D/C/F/TAF-FDC Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 1 placebo tablet matching the D/C/F/TAF 800/150/200/10 mg FDC on Day 1.

Investigational medicinal product name	DRV/COBI-FDC Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 1 placebo tablet matching the DRV/COBI 800/150 milligram (mg) FDC on Day 1.

<b>Arm title</b>	DRV/COBI FDC Placebo followed by D/C/F/TAF FDC Placebo
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Arm description:

Subjects received 1 placebo tablet matching the DRV/COBI 800/150 milligram (mg) FDC (Intake 1) and 1 placebo tablet matching the D/C/F/TAF 800/150/200/10 mg FDC (Intake 2) on Day 1. Both the intakes were separated by at least 30 minutes.

Arm type	Experimental
Investigational medicinal product name	DRV/COBI-FDC Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 1 placebo tablet matching the DRV/COBI 800/150 milligram (mg) FDC on Day 1.

Investigational medicinal product name	D/C/F/TAF-FDC Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 1 placebo tablet matching the D/C/F/TAF 800/150/200/10 mg FDC on Day 1.

<b>Number of subjects in period 1</b>	D/C/F/TAF FDC placebo followed by DRV/COBI FDC placebo	DRV/COBI FDC Placebo followed by D/C/F/TAF FDC Placebo
Started	12	15
Completed	12	15

## Baseline characteristics

### Reporting groups

Reporting group title	D/C/F/TAF FDC placebo followed by DRV/COBI FDC placebo
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Reporting group description:

Subjects received 1 placebo tablet matching the D/C/F/TAF 800/150/200/10 mg FDC (Intake 1) and 1 placebo tablet matching the DRV/COBI FDC (Intake 2) on Day 1. Both the intakes were separated by at least 30 minutes.

Reporting group title	DRV/COBI FDC Placebo followed by D/C/F/TAF FDC Placebo
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Reporting group description:

Subjects received 1 placebo tablet matching the DRV/COBI 800/150 milligram (mg) FDC (Intake 1) and 1 placebo tablet matching the D/C/F/TAF 800/150/200/10 mg FDC (Intake 2) on Day 1. Both the intakes were separated by at least 30 minutes.

Reporting group values	D/C/F/TAF FDC placebo followed by DRV/COBI FDC placebo	DRV/COBI FDC Placebo followed by D/C/F/TAF FDC Placebo	Total
Number of subjects	12	15	27
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	12	15	27
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	14.3	15.1	
standard deviation	± 1.60	± 1.62	-
Gender Categorical Units: Subjects			
Female	6	7	13
Male	6	8	14

## End points

### End points reporting groups

Reporting group title	D/C/F/TAF FDC placebo followed by DRV/COBI FDC placebo
Reporting group description: Subjects received 1 placebo tablet matching the D/C/F/TAF 800/150/200/10 mg FDC (Intake 1) and 1 placebo tablet matching the DRV/COBI FDC (Intake 2) on Day 1. Both the intakes were separated by at least 30 minutes.	
Reporting group title	DRV/COBI FDC Placebo followed by D/C/F/TAF FDC Placebo
Reporting group description: Subjects received 1 placebo tablet matching the DRV/COBI 800/150 milligram (mg) FDC (Intake 1) and 1 placebo tablet matching the D/C/F/TAF 800/150/200/10 mg FDC (Intake 2) on Day 1. Both the intakes were separated by at least 30 minutes.	
Subject analysis set title	D/C/F/TAF-FDC Placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description: Subjects received 1 placebo tablet matching the D/C/F/TAF 800/150/200/10 mg FDC.	
Subject analysis set title	DRV/COBI-FDC Placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description: Subjects received 1 placebo tablet matching the DRV/COBI 800/150 milligram (mg) FDC.	

### Primary: Acceptability of Swallowing Fixed-Dose Combination (FDC) Tablets in Human Immunodeficiency Virus (HIV)-1 Infected Adolescent Subjects

End point title	Acceptability of Swallowing Fixed-Dose Combination (FDC) Tablets in Human Immunodeficiency Virus (HIV)-1 Infected Adolescent Subjects <sup>[1]</sup>
End point description: Swallowability was assessed based on a 7-point questionnaire indicating how difficult/easy it was to swallow the tablet, ranging from "very difficult" to "very easy". The acceptability proportion is obtained by a dichotomization of the acceptability/swallowability scale, i.e. 'slightly difficult' or worse versus 'neither difficult nor easy' or better. The intent-to-treat (ITT) population included all the subjects who were randomized and received at least 1 dose of treatment subsequent to randomization in the study.	
End point type	Primary
End point timeframe: Day 1	

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: Only descriptive statistical analysis was performed for this outcome measure.

End point values	D/C/F/TAF-FDC Placebo	DRV/COBI-FDC Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	27	27		
Units: Percentage of subjects				
number (confidence interval 95%)				
Acceptable	92.6 (75.7 to 99.1)	100 (87.2 to 100)		

## Statistical analyses

No statistical analyses for this end point

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**Secondary: Acceptability of Daily Intake of the FDC Tablets, by HIV-1 Infected Adolescent Subjects**

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End point title	Acceptability of Daily Intake of the FDC Tablets, by HIV-1 Infected Adolescent Subjects
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End point description:

Acceptability for long term daily use will be assessed based on a 3-point questionnaire, 'not acceptable', 'acceptable', or 'good to take'. The ITT population included all the subjects who were randomized and received at least 1 dose of treatment subsequent to randomization in the study.

End point type	Secondary
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End point timeframe:

Day 1

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End point values	D/C/F/TAF-FDC Placebo	DRV/COBI-FDC Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	27	27		
Units: subjects				
Good to take	14	15		
acceptable	11	12		
not acceptable	2	0		

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**Statistical analyses**

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No statistical analyses for this end point

## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:

22 Days

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	v20.0
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### Reporting groups

Reporting group title	D/C/F/TAF-FDC placebo
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Reporting group description:

Subjects received 1 placebo tablet matching the D/C/F/TAF 800/150/200/10 mg FDC (Intake 1) and 1 placebo tablet matching the DRV/COBI FDC (Intake 2) on Day 1. Both the intakes were separated by at least 30 minutes.

Reporting group title	DRV/COBI-FDC Placebo
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Reporting group description:

Subjects received 1 placebo tablet matching the DRV/COBI 800/150 milligram (mg) FDC (Intake 1) and 1 placebo tablet matching the D/C/F/TAF 800/150/200/10 mg FDC (Intake 2) on Day 1. Both the intakes were separated by at least 30 minutes.

Serious adverse events	D/C/F/TAF-FDC placebo	DRV/COBI-FDC Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 15 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	D/C/F/TAF-FDC placebo	DRV/COBI-FDC Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 15 (0.00%)	

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: No adverse events were observed for this study.



## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported