



Clinical trial results:

Virological and immunological safety of a dose reduction strategy antiretroviral regimen with efavirenz / tenofovir / emtricitabine

Summary

EudraCT number	2012-004970-24
Trial protocol	ES
Global end of trial date	21 July 2015

Results information

Result version number	v1 (current)
This version publication date	09 August 2025
First version publication date	09 August 2025

Trial information

Trial identification

Sponsor protocol code	A-TRI-WEEK
-----------------------	------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01778413
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Fundació Clínic per a la Recerca Biomèdica
Sponsor organisation address	C. Roselló, 143, Barcelona, Spain,
Public contact	Anna Cruceta, CTU- Clinical Trial unit. Farmacologia clinica, ACRUCETA@recerca.clinic.cat
Scientific contact	Anna Cruceta, CTU- Clinical Trial unit. Farmacologia clinica, ACRUCETA@recerca.clinic.cat

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	21 July 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 November 2014
Global end of trial reached?	Yes
Global end of trial date	21 July 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to determine the feasibility of maintaining virologic suppression on standard plasma viral load (limit of detection 37 copies / mL) of a dose reduction strategy of ATRIPLA ® once a day to three tablets per weeks in patients infected with HIV-1 with sustained suppression of plasma viral load standard for more than two years.

Protection of trial subjects:

The study followed the Declaration of Helsinki and Spanish regulations (RD 223/2004).

Approval was obtained from the Ethics Committee and AEMPS before initiation.

Participants gave written informed consent after receiving oral and written information.

Confidentiality was ensured through coded data and restricted access.

Civil liability insurance was contracted by the sponsor.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2013
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: 61
Worldwide total number of subjects	61
EEA total number of subjects	61

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)	61
From 65 to 84 years	0

85 years and over	0
-------------------	---

Subject disposition

Recruitment

Recruitment details:

The study planned to recruit 60 adult HIV-1-infected patients with sustained virologic suppression on ATRIPLA® for over 2 years. Recruitment was conducted at a single center (Hospital Clínic de Barcelona) over a 12-month period. All participants provided written informed consent prior to any study procedures.

Pre-assignment

Screening details:

Screening included verification of inclusion/exclusion criteria, medical history, physical exam, vital signs, and laboratory tests. Eligible patients were randomized after baseline assessments.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Atripla OD

Arm description:

Atripla (600 mg/200 mg/245 mg) one time a day.

Arm type	Active comparator
Investigational medicinal product name	ATRIPLA
Investigational medicinal product code	
Other name	Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Once daily

Arm title	Atripla 3W
------------------	------------

Arm description:

Atripla (600 mg/200 mg/245 mg) three days a week (Mondays, Wednesdays and Fridays).

Arm type	Experimental
Investigational medicinal product name	ATRIPLA
Investigational medicinal product code	
Other name	Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants will receive one tablet of ATRIPLA® (600 mg efavirenz / 200 mg emtricitabine / 245 mg tenofovir disoproxil fumarate) orally, three times per week (on Monday, Wednesday, and Friday) for a total of 24 weeks.

Number of subjects in period 1	Atripla OD	Atripla 3W
Started	31	30
Completed	31	30

Baseline characteristics

Reporting groups

Reporting group title	Atripla OD
-----------------------	------------

Reporting group description:

Atripla (600 mg/200 mg/245 mg) one time a day.

Reporting group title	Atripla 3W
-----------------------	------------

Reporting group description:

Atripla (600 mg/200 mg/245 mg) three days a week (Mondays, Wednesdays and Fridays).

Reporting group values	Atripla OD	Atripla 3W	Total
Number of subjects	31	30	61
Age categorical 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)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
median	48.5	47.8	
inter-quartile range (Q1-Q3)	38.1 to 58.3	37.4 to 53.8	-
Gender categorical Units: Subjects			
Female	4	3	7
Male	27	27	54

End points

End points reporting groups

Reporting group title	Atripla OD
Reporting group description: Atripla (600 mg/200 mg/245 mg) one time a day.	
Reporting group title	Atripla 3W
Reporting group description: Atripla (600 mg/200 mg/245 mg) three days a week (Mondays, Wednesdays and Fridays).	

Primary: Proportion of Patients Free of Treatment Failure (Noncompleter = Failure) at 24 Weeks

End point title	Proportion of Patients Free of Treatment Failure (Noncompleter = Failure) at 24 Weeks ^[1]
End point description: Treatment failure defined as any of the following possibilities occurring within the 24-week study framework: virological failure (confirmed plasma viral load 37 copies/ml), discontinuation of the antiretroviral therapy schedule irrespective of the reason, consent withdrawal, lost to follow-up, pregnancy, inability to comply with the study or any other reason that could make the doctor in charge consider the cessation of the study.	
End point type	Primary
End point timeframe: 24 weeks	

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 formal statistical hypothesis test was performed for the primary endpoint because all patients in both arms (OD and 3W) remained free of treatment failure at 24 weeks. As there were zero events in both groups, a p-value was not applicable. A 95% confidence interval for the difference in proportions was estimated using Newcombe's method.

End point values	Atripla OD	Atripla 3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	30		
Units: Percentage (%)				
Virological failure	0	0		
Virological success	31	30		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

24 weeks

Adverse event reporting additional description:

Adverse Event Reporting Description AE/SAE definitions were consistent with ClinicalTrials.gov, but also included clinically significant lab abnormalities and events related to overdose, abuse, or withdrawal. AEs were collected systematically at baseline, weeks 12 and 24 in both arms, and at weeks 1, 2, 4, 6, and 8 in the 3-day/week arm. Gradi

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	DAIDS Table
-----------------	-------------

Dictionary version	1.0
--------------------	-----

Reporting groups

Reporting group title	ATRIPLA 3W
-----------------------	------------

Reporting group description: -

Reporting group title	ATRIPLA 0D
-----------------------	------------

Reporting group description: -

Serious adverse events	ATRIPLA 3W	ATRIPLA 0D	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 30 (0.00%)	0 / 31 (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	ATRIPLA 3W	ATRIPLA 0D	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 30 (43.33%)	11 / 31 (35.48%)	
General disorders and administration site conditions			
Mild, non-serious adverse events			
subjects affected / exposed	13 / 30 (43.33%)	11 / 31 (35.48%)	
occurrences (all)	13	11	

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.

Small sample size and short follow-up. All participants were stable on Atripla, limiting generalizability to other regimens or populations. No economic evaluation included.
--

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/29746294>