Clinical trial results:
A multi-centre, non-controlled, non-randomised IST to evaluate the plasma level of antiretroviral substances, the viral resistance profile and their impact on the clinical response in HIV infected children.

Summary

EudraCT number	2010-021624-99
Trial protocol	DE
Global end of trial date	23 June 2016

Results information

Result version number	v1 (current)
This version publication date	15 December 2022
First version publication date	15 December 2022

Trial information

Trial identification

Sponsor protocol code	HIV-TDM-GT Kids

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Goethe University Frankfurt
Sponsor organisation address	Theodor-Stern-Kai 7, Frankfurt am Main, Germany, 60590
Public contact	PD Dr. Dr. Christoph Koenigs, University Hospital Frankfurt, Goethe University , 0049 69630183030, Christoph.Koenigs@kgu.de
Scientific contact	PD Dr. Dr. Christoph Koenigs, University Hospital Frankfurt, Goethe University , 6963016998 69630183030, Christoph.Koenigs@kgu.de

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	03 November 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 June 2016
Global end of trial reached?	Yes
Global end of trial date	23 June 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of the study is to correlate the achieved plasma levels of lopinavir/r or darunavir/r with the success of therapy, taking into account the viral resistance profiles in HIV-infected children and adolescents.

Protection of trial subjects:

The study design involved a retrospective and prospective part. Thanks to the retrospective data, patients had a reduced burden. In the prospective part, outpatient visits were combined with those ones that the patients would have taken on their usual schedule, keeping blood sampling, additional visits than routine care at a minimum.

Background therapy:

The ART „backbone" therapy was administered according to the weight and age of the patients, according to valid guidelines. Most children received Combivir® (AZT/3CT), followed by Kivexa® (ABC/3TC), Truvada® (TDF/FTC) and finally a combination of Viread® and Ziagen® (TDF/ABC).

Evidence for comparator: -

Actual start date of recruitment	03 May 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	Germany: 17
Worldwide total number of subjects	17
EEA total number of subjects	17

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)	1
Children (2-11 years)	8
Adolescents (12-17 years)	8

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:

Patients with disease under investigation have been screened

Pre-assignment period milestones

Number of subjects started	17
Number of subjects completed	17

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Kaletra <12 years of age

Arm description: -

Arm type	Kaletra <12 years of age
Investigational medicinal product name	Kaletra
Investigational medicinal product code	J05AR10
Other name	Lopinavir/r
Pharmaceutical forms	Oral solution, Tablet
Routes of administration	Oral use

Dosage and administration details:

Dosage according to product information and weight of the patients

Arm title	Kaletra 12 -17 years of age

Arm description: -

Arm type	Kaletra >12 years of age
Investigational medicinal product name	Kaletra
Investigational medicinal product code	J05AR10
Other name	Lopinavir/r
Pharmaceutical forms	Tablet, Oral solution
Routes of administration	Oral use

Dosage and administration details:

Dosage according to product information and weight of the patients

Number of subjects in period 1	Kaletra <12 years of age	Kaletra 12 -17 years of age
Started	8	9
Completed	8	6
Not completed	0	3
Physician decision	-	3

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	17	17	
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)	1	1	
Children (2-11 years)	8	8	
Adolescents (12-17 years)	8	8	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
median	9		
full range (min-max)	1.58 to 17	-	
Gender categorical Units: Subjects			
Female	9	9	
Male	8	8	

End points

End points reporting groups

Reporting group title	Kaletra <12 years of age
Reporting group description: -	
Reporting group title	Kaletra 12 -17 years of age
Reporting group description: -	

Primary: Viral load

End point title	Viral load[1]

End point description:

The primary endpoint is the number of children with virological failure during the study period, where failure is defined as two consecutive viral loads >1000 copies/ml or a viral load drop after initiation of therapy and the correlation to pharmacological parameters and genotypic resistance.

End point type	Primary

End point timeframe:

Whole study period

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 statistics

End point values	Kaletra <12 years of age	Kaletra 12 -17 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	9		
Units: No of subjects with VL > 1000copies/ml				
number (not applicable)	2	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: overall study	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	DAIDS
Dictionary version	2004

Reporting groups	
Reporting group title	all patients

Reporting group description: -

Serious adverse events	all patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 17 (11.76%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Surgical and medical procedures			
Portexplantation			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	all patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 17 (100.00%)		
Gastrointestinal disorders			
Gastoenteritis			
subjects affected / exposed	12 / 17 (70.59%)		
occurrences (all)	24		
Respiratory, thoracic and mediastinal disorders			
cold	Additional description: common cold, cough, sore throat		
subjects affected / exposed	15 / 17 (88.24%)		
occurrences (all)	92		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
31 July 2013	Amendment 01, Substantial Amendment Notification Form 31Jul2013, Modul 1 31Jul2013, Protocol V4.0 30.Jul.2013, ICFs Carer V4.0 30Jul2013, ICFs patients V3.0 30Jul2013, IB PREZISTA Jan2013 (75mg, 150mg, 400mg, 600mg, 100mg/ml Suspension)
16 April 2015	Amendment 02, DAIDS Grading Scale V 2.0 Nov 2014, Protocol V5.0 16.Apr.2014, ICFs Carer V5.0 16Apr2015, ICFs patients V4.0 16Apr2015, Modul 1 23.Apr.2015, Substantial Amendment Notification Form 23Apr2015

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported