Clinical trial results:
Efficacy of Lopinavir in Pregnancy: Pharmacokinetic and Virological Studies with Kaletra melt extruded tablet formulation

Summary

EudraCT number	2007-000438-38
Trial protocol	GB
Global end of trial date	28 July 2010

Results information

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

Trial information

Trial identification

Sponsor protocol code	CRO 682

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Imperial College London
Sponsor organisation address	Norfolk Place, London, United Kingdom, W2 1PG
Public contact	Graham Taylor, Imperial College London, +44 02075943910, g.p.taylor@imperial.ac.uk
Scientific contact	Graham Taylor, Imperial College London, +44 02075943910, g.p.taylor@imperial.ac.uk

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	31 August 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 January 2010
Global end of trial reached?	Yes
Global end of trial date	28 July 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the plasma concentrations of lopinavir during pregnancy (when adminstered as a film coated tablet).

Protection of trial subjects:

No specific protection.

Background therapy:

General therapy

Evidence for comparator: -

Actual start date of recruitment	03 July 2006
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	United Kingdom: 11
Worldwide total number of subjects	11
EEA total number of subjects	11

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)	11
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participant were recruited at St Mary Hospital between 01.06.2006-31.01.2010.

Pre-assignment

Screening details:

A total of 11 pregnant participant with HIV taking lopinavir enrolled to the study.

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	All participant taking Lopinavir

Arm description:

All participant taking Lopinavir 400mg twice a day (weeks 13 through pregnancy to 8 weeks postpartum)

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

Dosage and administration details:

400mg twice a day

Number of subjects in period 1	All participant taking Lopinavir
Started	11
Completed	11

Baseline characteristics

Reporting groups

Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	11	11	
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)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	11	11	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
median	31.6		
full range (min-max)	19.5 to 41.6	-	
Gender categorical Units: Subjects			
Female	11	11	
Male	0	0	

End points

End points reporting groups

Reporting group title	All participant taking Lopinavir
Reporting group description:	
All participant taking Lopinavir 400mg twice a day (weeks 13 through pregnancy to 8 weeks postpartum)	
Subject analysis set title	Trimester 1
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Measurement of the concentration at Trimester 1	
Subject analysis set title	Trimester 2
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Measurement of the concentration at Trimester 2	
Subject analysis set title	Trimester 3
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Measurement of the concentration at Trimester 3	
Subject analysis set title	Postpartum
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Measurement of the concentration at Postpartum	

Primary: Concentration of the Lopinavir in plasma

End point title	Concentration of the Lopinavir in plasma
End point description:	
End point type	Primary
End point timeframe:	
Trimester 1, 2, 3, and postpartum	

End point values	Trimester 1	Trimester 2	Trimester 3	Postpartum
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	6	11	5
Units: ng/ml				
geometric mean (confidence interval 95%)	4889 (3836 to 6085)	4420 (3715 to 5290)	2505 (2008 to 3488)	4654 (3054 to 6786)

Statistical analyses

Statistical analysis title	Concentration differences in T1 vs. T3
Comparison groups	Trimester 1 v Trimester 3

Number of subjects included in analysis	14
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008
Method	ANOVA

Statistical analysis title	Concentration differences in T3 vs. postpartum
Comparison groups	Trimester 3 v Postpartum
Number of subjects included in analysis	16
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	ANOVA

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

3 years

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10

Reporting groups

Reporting group title	Overall study

Reporting group description: -

Serious adverse events	Overall study		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 11 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Overall study		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 11 (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 event recorded.

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/22106215