Clinical trial results:
Maraviroc Add-on Therapy for Steatohepatitis in HIV

Summary

EudraCT number	2017-003172-32
Trial protocol	DE GB
Global end of trial date	01 March 2020

Results information

Result version number	v1 (current)
This version publication date	03 November 2022
First version publication date	03 November 2022

Trial information

Trial identification

Sponsor protocol code	MASHVs1.118-08-17

Additional study identifiers

ISRCTN number	ISRCTN15410818
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Imperial College London
Sponsor organisation address	Exhibition Rd, London, United Kingdom,
Public contact	James Maurice, Imperial College London, james.maurice@imperial.ac.uk
Scientific contact	James Maurice, Imperial College London, james.maurice@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	01 March 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 March 2020
Global end of trial reached?	Yes
Global end of trial date	01 March 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Does maraviroc change the inflammatory cell infiltrate in the livers of patients with HIV infection and non-alcoholic steatohepatitis?

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 December 2017
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: 7
Country: Number of subjects enrolled	Germany: 7
Worldwide total number of subjects	14
EEA total number of subjects	7

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)	14
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Adult patients between the age of 18 and 75 and history of HIV-1 mono-infection with histological evidence of NASH, based on liver histology performed within 12 months before visit
HIV infection treated and controlled

Period 1

Period 1 title	Baseline
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

NA

Arms

Arm title	Single arm

Arm description:

Add on Maraviroc: patients received 150mg, 300mg, or 600mg of Maraviroc taken twice daily for 48 weeks as add-on therapy with the dosing adjusted for any drug interactions

Arm type	proof of concept study
Investigational medicinal product name	Maraviroc
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

150mg, 300mg, or 600mg of Maraviroc taken twice daily for 48 weeks as add-on therapy with the dosing adjusted for any drug interactions

Number of subjects in period 1	Single arm
Started	14
Completed	14

Period 2

Period 2 title	Endline
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

N/A

Arms

Arm title	Single arm

Arm description:

Add on Maraviroc: patients received 150mg, 300mg, or 600mg of Maraviroc taken twice daily for 48 weeks as add-on therapy with the dosing adjusted for any drug interactions

Arm type	proof of concept study
Investigational medicinal product name	Maraviroc
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

150mg, 300mg, or 600mg of Maraviroc taken twice daily for 48 weeks as add-on therapy with the dosing adjusted for any drug interactions

Number of subjects in period 2	Single arm
Started	14
Completed	14

Baseline characteristics

Reporting groups	
Reporting group title	Baseline

Reporting group description: -

Reporting group values	Baseline	Total	
Number of subjects	14	14	
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			
50.5 (43-59)			
Units: years			
median	50.5		
inter-quartile range (Q1-Q3)	43 to 59	-	
Gender categorical Units: Subjects			
Female	0	0	
Male	14	14	

End points

End points reporting groups

Reporting group title	Single arm
Reporting group description:	
Add on Maraviroc: patients received 150mg, 300mg, or 600mg of Maraviroc taken twice daily for 48 weeks as add-on therapy with the dosing adjusted for any drug interactions	
Reporting group title	Single arm
Reporting group description:	
Add on Maraviroc: patients received 150mg, 300mg, or 600mg of Maraviroc taken twice daily for 48 weeks as add-on therapy with the dosing adjusted for any drug interactions	
Subject analysis set title	primary endpoint
Subject analysis set type	Full analysis
Subject analysis set description:	
the change in hepatic immune cell and inflammatory infiltrate of the HIV-NASH patients to determine the efficacy of Maraviroc in treating such cases.	

Primary: primary endpoint

End point title	primary endpoint[1]
End point description:	
the change in hepatic immune cell and inflammatory infiltrate of the HIV-NASH patients	
End point type	Primary
End point timeframe:	
48 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: the change in hepatic immune cell and inflammatory infiltrate of the HIV-NASH patients to determine the efficacy of Maraviroc in treating such cases using paired liver biopsy

The endpoint has not been reached since no statistical difference was observed after treatment with Maraviroc compared to baseline liver histology

End point values	primary endpoint			
Subject group type	Subject analysis set			
Number of subjects analysed	14[2]			
Units: number of cells per liver tissue				
number (not applicable)	14			

Notes:

[2] - one patient did not get the second liver biopsy

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 48 weeks	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1.0

Reporting groups	
Reporting group title	study participants

Reporting group description: -

Serious adverse events	study participants		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 14 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	study participants		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 14 (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: None

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