Clinical trial results:
A prospective, observational study to examine the effects of ageing on the clinical outcomes of people living with HIV in England and Ireland.

Summary

EudraCT number	2012-003581-40
Trial protocol	GB IE
Global end of trial date	31 March 2023

Results information

Result version number	v1 (current)
This version publication date	09 May 2024
First version publication date	09 May 2024
Summary attachment (see zip file)	POPPY Results (POPPY 1-3 Publication Cohort Profile.pdf) POPPY Results (POPPY 1-3 Publication Cohort Profile.pdf)

Trial information

Trial identification

Sponsor protocol code	CRO1992

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01737047
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Imperial College London
Sponsor organisation address	Imperial College Clinical Trials Unit, 1st Floor, Stadium House, 68 Wood Lane, London, United Kingdom, W12 7RH
Public contact	Alan Winston, Alan Winston, 0044 2033121603, a.winston@imperial.ac.uk
Scientific contact	Alan Winston, Imperial College London, 0044 2033121603, a.winston@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 March 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 March 2023
Global end of trial reached?	Yes
Global end of trial date	31 March 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To analyse the incidence and outcomes of intercurrent illnesses (other illnesses occurring or recurring) in older HIV-positive people and their relationship with demographic(for example age, gender, ethnicity employment, housing and relationship status) and clinical factors (for example any details of past or present illnesses and treatments). Also history of illnesses within the family.

Protection of trial subjects:

Informed Consent obtained. Regulatory Approval including ethics obtained. Steering Committee reviewed trial conduct and patients safety.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 April 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	United Kingdom: 1296
Country: Number of subjects enrolled	Ireland: 81
Worldwide total number of subjects	1377
EEA total number of subjects	81

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)	1200
From 65 to 84 years	175

85 years and over	2

Subject disposition

Recruitment

Recruitment details:

Recruited through HIV clinics

Pre-assignment

Screening details:

Participants were recruited via participant sites (HIV clinics), screened and consented to join the study

Pre-assignment period milestones

Number of subjects started	1377
Number of subjects completed	1377

Period 1

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

Blinding implementation details:

Not applicable

Arms

Are arms mutually exclusive?	Yes
Arm title	Older PWLH

Arm description:

Not applicable

Arm type	Not applicable
Investigational medicinal product name	Not applicable
Investigational medicinal product code	Not applicable
Other name	Not applicable
Pharmaceutical forms	Not assigned
Routes of administration	Unknown use

Dosage and administration details:

Not applicable

Arm title	Younger PWLH

Arm description: -

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	HIV-Negative

Arm description: -

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Older PWLH	Younger PWLH	HIV-Negative
Started	699	374	304
Not applicable	699	-	-
Completed	699	374	304

Baseline characteristics

Reporting groups	
Reporting group title	Older PWLH
Reporting group description:	
Not applicable	
Reporting group title	Younger PWLH
Reporting group description: -	
Reporting group title	HIV-Negative
Reporting group description: -	

Reporting group values	Older PWLH	Younger PWLH	HIV-Negative
Number of subjects	699	374	304
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
Units: years			
median	57	43	58
inter-quartile range (Q1-Q3)	53 to 62	37 to 47	53 to 63
Gender categorical			
Units: Subjects			
Female	87	72	109
Male	612	302	195

Reporting group values	Total		
Number of subjects	1377		
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 inter-quartile range (Q1-Q3)	- 		
Gender categorical Units: Subjects			
Female	268		
Male	1109		

End points

End points reporting groups	
Reporting group title	Older PWLH
Reporting group description: Not applicable	
Reporting group title	Younger PWLH
Reporting group description: -	
Reporting group title	HIV-Negative
Reporting group description: -	
Subject analysis set title	N/A
Subject analysis set type	Per protocol
Subject analysis set description: N/A	

Primary: Not applicable	
End point title	Not applicable
End point description: Not applicable	
End point type	Primary
End point timeframe: Not applicable	

End point values	Older PWLH	Younger PWLH	HIV-Negative	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	699[1]	374[2]	304[3]	
Units: Not applicable				
Not applicable	0	0	0	

Notes:
[1] - Not applicable
[2] - Not applicable
[3] - Not applicable

Statistical analyses

Statistical analysis title	Not applicable
Statistical analysis description: Not applicable	
Comparison groups	Older PWLH v Younger PWLH v HIV-Negative
Number of subjects included in analysis	1377
Analysis specification	Pre-specified
Analysis type	other[4]
P-value	< 1 [5]
Method	Not applicable
Parameter estimate	Not applicable
Point estimate	0

Confidence interval	
level	Other: 0 %
sides	2-sided
lower limit	0
upper limit	1
Variability estimate	Standard deviation
Dispersion value	0

Notes:

[4] - Not applicable

[5] - Not applicable

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
From consent to visit 3	
Adverse event reporting additional description:	
Non-serious adverse events were not reported for this study.	
Assessment type	Systematic

Dictionary used	
Dictionary name	Not coded
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 1 %

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: Non-serious adverse events were not reported for this study.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 February 2013	Addition of letter of invitation to participant
04 April 2013	HIV negative subjects can attend visit 2 in person
21 June 2013	Addition of short summary of information sheet for the HIV+ve participants
10 September 2013	Addition of short summary of information sheet for the HIV+ve participants
09 December 2013	Twitter account introduced for adverts
17 December 2013	Allow recruitment from POPPY cohort for other sub-studies (special interest groups)
07 April 2014	New recruitment material to target the HIV negative group
08 May 2014	Not to perform neurocognitive computerised tests at the 2nd year follow up visit
26 May 2015	Change in PI at Brighton
08 September 2015	Change in PI at Brighton & addition of RFH
24 August 2016	Change in Trial Manager Addition of respiratory questionnaire Removal of NC at visit 2 and removal of PE
20 December 2016	IRISH HPRA ONLY: Removal of all IMPs (with the exception of Viread) from Irish CTA form and updated details
22 June 2017	UK only: Addition of end of trial definition
03 July 2017	Irish site only: Addition of end of trial definition

Notes:

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.

The POPPY Trial is not a CTIMP but in 2012 was classified by the MHRA as a CTIMP. It is only an observational study and has been assessing clinical outcomes of people living with HIV (PLWH) over the age of 50 in England and Ireland.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/29746638