



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 |

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 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 | 0 0 0 0 0 0 0 0 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>