# Clinical trial results:
# Removal of dolutegravir by hemodialysis in HIV-infected patients with end-stage renal disease.

## Summary

| | |
|---|---|
| EudraCT number | 2015-000856-16 |
| Trial protocol | ES |
| Global end of trial date | 03 July 2015 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 11 August 2017 |
| First version publication date | 11 August 2017 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | DTG_HD |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02487706 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | Fundació Lluita contra la SIDA |
| Sponsor organisation address | Crta de Canyet s/n, Badalona, Spain, 08916 |
| Public contact | Unitat VIH, Fundació Lluita contra la SIDA, +34 93497 84 14, rescrig@flsida.org |
| Scientific contact | Unitat VIH, Fundació Lluita contra la SIDA, +34 93497 84 14, rescrig@flsida.org |

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 July 2015 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 03 July 2015 |
| Global end of trial reached? | Yes |
| Global end of trial date | 03 July 2015 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

To evaluate hemodialysis extraction ratio and clearance of dolutegravir in HIV-infected patients with end-stage renal disease.

Protection of trial subjects:

not specific

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 22 June 2015 |
| 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 | Spain: 5 |
| Worldwide total number of subjects | 5 |
| EEA total number of subjects | 5 |

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) | 5 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Five anuric HIV-infected patients were enrolled.

### Period 1

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

### Arms

| | |
|---|---|
| **Arm title** | Experimenal arm |

Arm description:

dolutegravir 50 mg once daily was added to their stable cART for five days.

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

Dosage and administration details:

50mg/day

| **Number of subjects in period 1** | Experimenal arm |
|---|---|
| Started | 5 |
| Completed | 5 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | overall |

Reporting group description: -

| Reporting group values | overall | Total | |
|---|---|---|---|
| Number of subjects | 5 | 5 | |
| Age categorical<br>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) | 5 | 5 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Age continuous<br>Units: years | | | |
| median | 53 | | |
| inter-quartile range (Q1-Q3) | 41.3 to 69.5 | - | |
| Gender categorical<br>Units: Subjects | | | |
| Female | 1 | 1 | |
| Male | 4 | 4 | |

## End points

### End points reporting groups

| Reporting group title | Experimenal arm |
|---|---|
| Reporting group description: dolutegravir 50 mg once daily was added to their stable cART for five days. | |

### Primary: Dolutegravir concentrations in plasma: concentration in plasma at the end of the dialysis session

| End point title | Dolutegravir concentrations in plasma: concentration in plasma at the end of the dialysis session[1] |
|---|---|
| End point description: | |
| End point type | Primary |
| End point timeframe: day 5 | |

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: Descriptive analysis of 5 patients. No comparisons were made

| End point values | Experimenal arm | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 5 | | | |
| Units: mg/l | | | | |
| median (full range (min-max)) | 1.89 (0.86 to 2.77) | | | |

### Statistical analyses

No statistical analyses for this end point

### Primary: hemodialysis extraction ratio

| End point title | hemodialysis extraction ratio[2] |
|---|---|
| End point description: | |
| End point type | Primary |
| End point timeframe: day 5 | |

Notes:

[2] - 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: Descriptive analysis of 5 patients. No comparisons were made

| End point values | Experimenal arm | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 5 | | | |
| Units: percentage (%) | | | | |
| median (inter-quartile range (Q1-Q3)) | 7 (1 to 25) | | | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

| Adverse events information[1] | |
|---|---|
| Timeframe for reporting adverse events: from baseline to day 5 | |
| Assessment type | Non-systematic |

| Dictionary used | |
|---|---|
| Dictionary name | DAIDS AE GRADING TAB |
| Dictionary version | 2.0 |

| Reporting groups | |
|---|---|
| Reporting group title | experimental arm |

Reporting group description: -

| Serious adverse events | experimental arm | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |

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

| Non-serious adverse events | experimental arm | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 5 (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: There were neither non-serious adverse events nor adverse events in this clinical trial.

## 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