# Clinical trial results:
# Phase II multicenter study of extracorporeal photopheresis with UvadexTM plus standard steroid treatment for high risk acute Graft-versus-Host Disease

## Summary

| | |
|---|---|
| EudraCT number | 2019-000894-22 |
| Trial protocol | DE AT |
| Global end of trial date | 24 June 2024 |

**Results information**

| | |
|---|---|
| Result version number | v2 (current) |
| This version publication date | 13 November 2026 |
| First version publication date | 19 June 2026 |
| Version creation reason | • Correction of full data set<br>Correction of data entry : Frequency Threshold for Reporting Adverse Events entered incorrectely. No thresholder applied. |
| Summary attachment (see zip file) | MAGIC-HR-ECP-CSR Synopsis (MAGIC-HR-ECP_CSR_Synopsis_Final_31_Mar_2026.pdf) |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | MAGIC-HR-ECP |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT04291261 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | University Medical Center Hamburg-Eppendorf |
| Sponsor organisation address | Martinistrasse 52, Hamburg, Germany, 20246 |
| Public contact | Francis A. Ayuk, Department of Stem Cell Transplantation - University Medical Center Hamburg-Eppendorf, 0049 40741055250, ayuketan@uke.de |
| Scientific contact | Francis A. Ayuk, Department of Stem Cell Transplantation - University Medical Center Hamburg-Eppendorf, 0049 40741055250, ayuketan@uke.de |

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 March 2025 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 24 June 2024 |
| Global end of trial reached? | Yes |
| Global end of trial date | 24 June 2024 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of the study was to improve Day 28 GvHD complete response rate for Ann Arbor score 2 or 3 GvHD patients from the historical rate of 37% to 52% by treatment with ECP and high dose methylprednisolone (2 mg/kg) or equivalent dose prednisolone.

Protection of trial subjects:

This study was conducted in accordance with applicable ICH/GCP regulations and guidelines, the general principles set forth in the Declaration of Helsinki, and all applicable regulatory requirements. Prior to the start of the study, the study protocol was reviewed and approved by an independent ethics committee (IEC).
Prior to any study-related procedures, subjects were informed by a principal investigator about all procedures and counseled regarding the risks and benefits of the study. Patients were always given sufficient time to ask questions and decide whether they wished to participate in the study. Prior to any study-related procedures, written informed consent was obtained from the patients and the approving investigators.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 11 March 2020 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Austria: 1 |
| Country: Number of subjects enrolled | Germany: 23 |
| Worldwide total number of subjects | 24 |
| EEA total number of subjects | 24 |

Notes:

### Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 | 0 |

| wk | |
|---|---|
| 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) | 19 |
| From 65 to 84 years | 5 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

This study was conducted in 3 sites in Germany and 1 site in Austria. The sites were located at university hospitals with a focus on stem cell transplantation .

### Pre-assignment

Screening details:

The screening process started after the patient was diagnosed with aGvHD (Glucksberg grade IIIV) following allogeneic SCT and after Informed Consent was collected. Sceening period time was Day -5 to Day 0. Patient eligibility was determined locally, except Ann Arbor scoring was measured centrally using standard technical procedures.

### Pre-assignment period milestones

| | |
|---|---|
| Number of subjects started | 52[1] |
| Number of subjects completed | 24 |

### Pre-assignment subject non-completion reasons

| | |
|---|---|
| Reason: Number of subjects | Consent withdrawn by subject: 1 |
| Reason: Number of subjects | Screening failures: 27 |

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Number started pre-assignment period are all screened patients. Number of worldwide enrolled are the patients who entered the trial for treatment (without screening failures).

### Period 1

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

### Arms

| | |
|---|---|
| **Arm title** | ECP plus standard steroid treatment |

Arm description:

Days 0-56: ECP 3x/week in Week 1 and Week 2. 2x/week in Week 3 and Week 4, then once weekly until Day 56.
Protocol treatment with ECP had to start within 5 working days (=7 days) after initiation of systemic steroid treatment for aGvHD. Dose of methylprednisolon 2 mg/kg/day orally or i.v. (or prednisone equivalent). The dose of steroids could not be tapered before 3 days of initiation of study therapy (=first ECP, defined as Day 0), but afterwards local institutional tapering practices could be followed.
Weeks 10, 12 and Months 6, 9, 12: Follow-up Period. Patients were followed 1 year after removal from treatment or intil death, whichever accures first.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | UVADEX |
| Investigational medicinal product code | |
| Other name | methoxsalen, 8-methoxypsoralen |
| Pharmaceutical forms | Solution for infusion in administration system |
| Routes of administration | Extracorporeal use |

Dosage and administration details:

UVADEX™ was supplied as a sterile solution containing methoxsalen 20 mcg, propylene glycol 50 mg, sodium chloride 8 mg, sodium acetate 1.75 mg, ethanol 40.550 mg, glacial acetic acid 1.260 mg, and water for injection q.s. to 1.0 mL. Glacial acetic acid and sodium hydroxide were used to adjust the pH of the solution if necessary.
UVADEX™ was provided and distributed to the individual sites by Therakos (Mallinckrodt).

The ECP procedure was be performed according to manufacturer’s guidelines.
For the treatment, photopheresis consisted of removing a portion of the patient's blood and separating the red blood cells from the white cell layer (buffy coat) by centrifugation. The red cells were returned to the patient and the UVADEX™ sterile solution was then injected into the photopheresis system and mixed with the buffy coat. The instrument then irradiated this drug-cell mixture with ultraviolet light (UVA light, 320-400 nm) and returned the treated cells to the patient.

| **Number of subjects in period 1** | ECP plus standard steroid treatment |
|---|---|
| Started | 24 |
| Completed | 21 |
| Not completed | 3 |
| Adverse event, serious fatal | 3 |

## Baseline characteristics

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

Reporting group description: -

| Reporting group values | overall trial | Total | |
|---|---|---|---|
| Number of subjects | 24 | 24 | |
| 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) | 19 | 19 | |
| From 65-84 years | 5 | 5 | |
| 85 years and over | 0 | 0 | |
| Gender categorical<br>Units: Subjects | | | |
| Female | 10 | 10 | |
| Male | 14 | 14 | |
| GvHD staging<br>Units: Subjects | | | |
| Grade II | 17 | 17 | |
| Grade III | 6 | 6 | |
| Grade IV | 1 | 1 | |
| Skin stages<br>Units: Subjects | | | |
| No rash | 4 | 4 | |
| Rash <25% BSA | 2 | 2 | |
| Rash 25-50% BSA | 4 | 4 | |
| > 50% generalized erythroderma | 14 | 14 | |
| Liver stages<br>Units: Subjects | | | |
| Bilirubin <2 mg/dl | 21 | 21 | |
| Bilirubin 2.1-3 mg/dl | 2 | 2 | |
| Bilirubin 3.1-6 mg/dl | 1 | 1 | |
| Gastrointestinal tract<br>Units: Subjects | | | |
| Diarrhea <500 ml/day | 10 | 10 | |
| Diarrhea 500-1000 ml/day or severe nausea/vomiting | 8 | 8 | |
| Diarrhea 1001-1500 ml/day | 4 | 4 | |
| Diarrhea >1500 ml/day | 1 | 1 | |
| severe abdominal pain with/without ileus, grossly | 1 | 1 | |

| | | | |
|---|---|---|---|
| Diagnosis for transplantation<br>Units: Subjects | | | |
| ALL | 2 | 2 | |
| AML | 10 | 10 | |
| CLL | 1 | 1 | |
| CML | 1 | 1 | |
| CMML | 1 | 1 | |
| CMML-2 | 1 | 1 | |
| DLCL | 1 | 1 | |
| Hodgkin's disease | 1 | 1 | |
| MDS | 4 | 4 | |
| MDS/MPN Overlap | 1 | 1 | |
| OMF | 1 | 1 | |
| Remission status at transplant<br>Units: Subjects | | | |
| Aplasia | 1 | 1 | |
| CR | 12 | 12 | |
| PD | 2 | 2 | |
| PR | 1 | 1 | |
| Primary refractory | 1 | 1 | |
| Relapse (after CR) | 1 | 1 | |
| Untreated | 6 | 6 | |
| Donor type<br>Units: Subjects | | | |
| Related | 1 | 1 | |
| Related (10/10) | 1 | 1 | |
| Related (Haplo) | 2 | 2 | |
| Related sibling (10/10) | 1 | 1 | |
| Unrelated (10/10) | 14 | 14 | |
| Unrelated (8/10) | 1 | 1 | |
| Unrelated (8/8) | 1 | 1 | |
| Unrelated (9/10) | 3 | 3 | |
| Donor/recipient HLA-matching<br>Units: Subjects | | | |
| Halfmatch | 1 | 1 | |
| Match | 17 | 17 | |
| Mismatch | 6 | 6 | |
| GvHD prophylaxis (condensed)<br>Units: Subjects | | | |
| CNI + MMF | 19 | 19 | |
| CNI + MMF + PTCy | 5 | 5 | |
| Ann Arbor Score<br>Units: none | | | |
| median | 2.0 | | |
| inter-quartile range (Q1-Q3) | 2.0 to 3.0 | - | |
| Days since transplantation at enrollment<br>Units: none | | | |
| median | 20.0 | | |
| inter-quartile range (Q1-Q3) | 13.5 to 22.5 | - | |
| HCT-CI score at transplant<br>Units: none | | | |

| | | | |
|---|---|---|---|
| median | 3.0 | | |
| inter-quartile range (Q1-Q3) | 3.0 to 6.0 | - | |

## End points

### End points reporting groups

| Reporting group title | ECP plus standard steroid treatment |
|---|---|

Reporting group description:

Days 0-56: ECP 3x/week in Week 1 and Week 2. 2x/week in Week 3 and Week 4, then once weekly until Day 56.
Protocol treatment with ECP had to start within 5 working days (=7 days) after initiation of systemic steroid treatment for aGvHD. Dose of methylprednisolon 2 mg/kg/day orally or i.v. (or prednisone equivalent). The dose of steroids could not be tapered before 3 days of initiation of study therapy (=first ECP, defined as Day 0), but afterwards local institutional tapering practices could be followed.
Weeks 10, 12 and Months 6, 9, 12: Follow-up Period. Patients were followed 1 year after removal from treatment or intil death, whichever accures first.

### Primary: Complete response at Day 28 of study treatment

| End point title | Complete response at Day 28 of study treatment[1] |
|---|---|

End point description:

The primary endpoint was the proportion of CR at Day 28 of study treatment. Death, lack of CR at Day 28, or initiation of additional immunosuppressive therapy were considered failures for this endpoint. The following values show the proportion of CR together with a two-sided 90% exact Clopper-Pearson confidence interval (CI) and the p-value for the comparison with the historical rate of 0.37.
p-value < 0.001:  for testing the null hypothesis that the CR rate is smaller or equal to the historical rate a binomial test with a one-sided type I error rate of 5% was used.

| End point type | Primary |
|---|---|

End point timeframe:

28 days after first ECP treatment (Day 0).

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: Details are given in the description.

| End point values | ECP plus standard steroid treatment | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 24[2] | | | |
| Units: proportion | | | | |
| number (confidence interval 90%) | | | | |
| proportion of complete response (CR) | 0.8750 (0.7077 to 0.9650) | | | |

Notes:

[2] - Full Analysis Set (FAS)

### Statistical analyses

No statistical analyses for this end point

### Secondary: Overall Response at Day 28

| End point title | Overall Response at Day 28 |
|---|---|

End point description:

Pre-defined binary secondary endpoints were overall response at day 28 and 56, defined as CR or PR at

day 28 and 56. Death, lack of CR/PR at the respective day or initiation of additional immunosuppressive therapy are considered as failures for this endpoint. The following values show the proportion of overall response at day 28 consisting of patients who
achieved partial or complete response together with a two-sided 95% exact Wilson-Score CI.

| End point type | Secondary |
|---|---|

End point timeframe:

Day 28 after first ECP treatment (Day 0)

| **End point values** | ECP plus standard steroid treatment | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 24[3] | | | |
| Units: proportion | | | | |
| number (confidence interval 95%) | | | | |
| Overall response at Day 28 | 0.9167 (0.7415 to 0.9768) | | | |

Notes:

[3] - Full analysis set

### Statistical analyses

No statistical analyses for this end point

## Secondary: Overall Response at Day 56

| End point title | Overall Response at Day 56 |
|---|---|

End point description:

Pre-defined binary secondary endpoints were overall response at day 28 and 56, defined as CR or PR at day 28 and 56. Death, lack of CR/PR at the respective day or initiation of additional immunosuppressive therapy are considered as failures for this endpoint. The following values show the proportion of overall response at day 56 consisting of patients who
achieved partial or complete response together with a two-sided 95% exact Wilson-Score CI.

| End point type | Secondary |
|---|---|

End point timeframe:

Day 56 after first ECP treatment (Day 0)

| **End point values** | ECP plus standard steroid treatment | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 23[4] | | | |
| Units: proportion | | | | |
| number (confidence interval 95%) | | | | |
| Overall response at Day 56 | 0.7826 (0.5810 to 0.9034) | | | |

Notes:

[4] - Full analysis set

## Statistical analyses

No statistical analyses for this end point

## Secondary: Overall survival at 1 year

| End point title | Overall survival at 1 year |
|---|---|

End point description:

For the secondary endpoint overall survival (OS) at 1 year, an administrative censoring was applied at 1 year after enrollment, if patients are observed longer. The following table shows the estimates for 1-year OS together with the 95%-CI using Kaplan-Meier estimation.

| End point type | Secondary |
|---|---|

End point timeframe:

1 year after enrollment

| **End point values** | ECP plus standard steroid treatment | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 24[5] | | | |
| Units: proportion | | | | |
| number (confidence interval 95%) | | | | |
| 1-year OS | 0.875 (0.661 to 0.958) | | | |

Notes:

[5] - Full analyis set

## Statistical analyses

No statistical analyses for this end point

## Secondary: Further time-to-event endpoints

| End point title | Further time-to-event endpoints |
|---|---|

End point description:

For all further time-to-event endpoints death (from any cause) was treated as competing event. The cumulative incidence at the respective timepoints was estimated using Aalen-Johansen estimators together with its 95%-CI. The following table shows the respective results.

| End point type | Secondary |
|---|---|

End point timeframe:

6 months / 12 months /Visit Day 28 (visit window until 33 days) / Visit Days 56 ( window until 66 days)

| End point values | ECP plus standard steroid treatment | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 24 | | | |
| Units: Incidence | | | | |
| number (confidence interval 95%) | | | | |
| NRM (6 months) | 0.083 (0.014 to 0.233) | | | |
| NRM (12 months) | 0.083 (0.014 to 0.233) | | | |
| Chronic GvHD (12 months) | 0.5 (0.291 to 0.678) | | | |
| Severe GI aGvHD (6 months) | 0.083 (0.014 to 0.233) | | | |
| Treatment-refractory GvHD (Visit Day 28) | 0.042 (0.003 to 0.176) | | | |
| Treatment-refractory GvHD (Visit Day 56) | 0.219 (0.062 to 0.436) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Safety endpoint - Relapse

| End point title | Safety endpoint - Relapse |
|---|---|

End point description:

The safety endpoints were analysed within the EFS population, which is equivalent to the FAS population. The following table shows the safety endpoint analysis for the endpoint "relapse" in the EFS/FAS population (Aalen-Johansen estimator).

| End point type | Secondary |
|---|---|

End point timeframe:

12 months

| End point values | ECP plus standard steroid treatment | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 24 | | | |
| Units: Incidence | | | | |
| number (confidence interval 95%) | | | | |
| Relapse | 0.042 (0.003 to 0.176) | | | |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Data on all events meeting the criteria and defintion of an AE with CTCAE grade 3 or higher or SAE were collected from the time of consenting until the patient's follow-up phase .

Adverse event reporting additional description:

For the Safety evaluation, AEs only during treatment (defined at time of ECP treatment + 28 days) were analysed and are listed below.
Only events with CTCAE grade 3 , 4 and 5 (severe AEs and SAEs) were analysed.

| | |
|---|---|
| Assessment type | Systematic |

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 28 |

### Reporting groups

| | |
|---|---|
| Reporting group title | Adverse events - Safety population |

Reporting group description:

Subjects affected during treatment (defined as time of ECP treatment + 28 days) and with CTCAE grade ≥3.

| Serious adverse events | Adverse events - Safety population | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 14 / 24 (58.33%) | | |
| number of deaths (all causes) | 1 | | |
| number of deaths resulting from adverse events | 1 | | |
| Injury, poisoning and procedural complications | | | |
| Pelvic fracture | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac disorders | | | |
| Cardiac arrest | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Immune system disorders | | | |
| Acute graft versus host disease | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 2 / 24 (8.33%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Renal and urinary disorders | | | | |
| Acute kidney injury | | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Musculoskeletal and connective tissue disorders | | | | |
| Myopathy | | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Synovitis | | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Infections and infestations | | | | |
| Infection | Additional description: unclear focus | | | |
| subjects affected / exposed | 3 / 24 (12.50%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sepsis | | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia | | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cytomegalivirus infection reactivation | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 24 (4.17%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Herpes simplex | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastroenteritis adenovirus | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metabolism and nutrition disorders | | | |
| Hyponatraemia | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Steroid diabetes | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| **Non-serious adverse events** | Adverse events - Safety population | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 13 / 24 (54.17%) | | |
| Blood and lymphatic system disorders | | | |
| Pancytopenia | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | |
| occurrences (all) | 1 | | |
| Thrombotic microangiopathy | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | |
| occurrences (all) | 1 | | |
| Anaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 24 (4.17%) | | |
| occurrences (all) | 1 | | |
| Immune system disorders | | | |
| Acute graft versus host disease | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | |
| occurrences (all) | 1 | | |
| Infections and infestations | | | |
| Infections | | | |
| subjects affected / exposed | 3 / 24 (12.50%) | | |
| occurrences (all) | 4 | | |
| Sepsis | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | |
| occurrences (all) | 1 | | |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | |
| occurrences (all) | 1 | | |
| Cytomegalovirus infection reactivation | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | |
| occurrences (all) | 1 | | |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | |
| occurrences (all) | 1 | | |
| Herpes simplex | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | |
| occurrences (all) | 1 | | |
| Metabolism and nutrition disorders | | | |
| Hyponatraemia | | | |
| subjects affected / exposed | 1 / 24 (4.17%) | | |
| occurrences (all) | 1 | | |

## 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