Clinical trial results:
A trial aimed at enhancing immunity to Influenza in elderly individuals through reversal of immune senescence mediated by herpes virus infection.

Summary

EudraCT number	2011-000092-13
Trial protocol	GB
Global end of trial date	21 March 2016

Results information

Result version number	v1 (current)
This version publication date	10 July 2022
First version publication date	10 July 2022

Trial information

Trial identification

Sponsor protocol code	RG_10-292

Additional study identifiers

ISRCTN number	ISRCTN24967173
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University of Birmingham
Sponsor organisation address	Room 119, Aston Webb Building, Edgbaston, , Birmingham, United Kingdom, B15 2TT
Public contact	Rachel Bruton , University of Birmingham , 44 01214148557, r.k.bruton@bham.ac.uk
Scientific contact	Professor Paul Moss, University of Birmingham , 44 01214142824, p.moss@bham.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	19 June 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 March 2016
Global end of trial reached?	Yes
Global end of trial date	21 March 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Part 1 : Feasibilty Study -The primary objective is to determine the efficacy of valaciclovir for reduction of the CMV-specific T cell response. Part 2 : Phase II Randomised Controlled Trial -The primary objective is to assess the value of valaciclovir in the augmentation of the immune response to influenza vaccination in donors aged ≥65 years.

Protection of trial subjects:

Inclusion /exclusion criteria and safety reporting as per the protocol. A trial steering committee was also appointed.

Background therapy:

N/A

Evidence for comparator:

(i) No treatment.
(ii) 500mg valaciclovir b.d.
(iii) 1000mg valaciclovir b.d.
(iv) 1000mg valaciclovir q.d.s.

The comparators are different doses and regimes of the anti-viral drug Valaciclovir.
The drug is licensed for suppression of CMV reactivation in a number of settings at a variety of concentrations. In the setting of renal transplantation a dose of 2gm q.d.s is associated with a profound reduction in the frequency of CMV reactivation. A dose of 1gm t.d.s in this setting has also shown efficacy in preventing viral reactivation. The drug has not been assessed for its ability to suppress CMV reactivation in immunocompetent donors and this is the subject of this study. The comparators were selected based on the lower range of that licensed in the clinical setting of immunosuppressed donors

Actual start date of recruitment	15 May 2012
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	United Kingdom: 38
Worldwide total number of subjects	38
EEA total number of subjects	0

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)	0
From 65 to 84 years	38
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The participants in the trial were recruited from GP surgeries within the West Midlands UK

Pre-assignment

Screening details:

102 individuals were assessed for eligibility
Not Eligible (N=54)
- o CMV negative (N=31)
- o Inadequate CD4+ / CD8+ response (N=5)
- o Current medication / disease / planned surgery / holiday commitments (N=12)
- o Results of routine screening blood tests (N=5)
- o Ineligible under the original study criteria (N=1)

Pre-assignment period milestones

Number of subjects started	38
Number of subjects completed	

Period 1

Period 1 title	milestone 1 (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Assessor[1]

Blinding implementation details:

This part of the study is single blind. Patients and the clinical team knew which treatment group they were in; the laboratory did not. An unblinding strategy was therefore not needed for this part of the study.

Arms

Are arms mutually exclusive?	Yes
Arm title	no treatment

Arm description:

no treatment

Arm type	Placebo
Investigational medicinal product name	placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

as perscribed

Arm title	valaciclovir 500mg b.d.

Arm description:

500mg Valaciclovir twice a day

Arm type	Active comparator

Investigational medicinal product name	valaciclovir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

500mg twice a day

Arm title	valaciclovir 1000mg b.d.

Arm description:

1000mg Valaciclovir twice a day

Arm type	Active comparator
Investigational medicinal product name	valaciclovir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1000mg twice a day

Arm title	valaciclovir 1000mg q.d.s.

Arm description:

1000mg Valaciclovir four times a day

Arm type	Active comparator
Investigational medicinal product name	valaciclovir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1000mg four times a day

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: This part of the study is single blind. Patients and the clinical team knew which treatment group they were in; the laboratory did not. In this case the laboratory staff have been classified as the assessor

Number of subjects in period 1	no treatment	valaciclovir 500mg b.d.	valaciclovir 1000mg b.d.
Started	10	7	10
Completed	10	7	10

Number of subjects in period 1	valaciclovir 1000mg q.d.s.
Started	11
Completed	11

Baseline characteristics

Reporting groups	
Reporting group title	no treatment
Reporting group description: no treatment	
Reporting group title	valaciclovir 500mg b.d.
Reporting group description: 500mg Valaciclovir twice a day	
Reporting group title	valaciclovir 1000mg b.d.
Reporting group description: 1000mg Valaciclovir twice a day	
Reporting group title	valaciclovir 1000mg q.d.s.
Reporting group description: 1000mg Valaciclovir four times a day	

Reporting group values	no treatment	valaciclovir 500mg b.d.	valaciclovir 1000mg b.d.
Number of subjects	10	7	10
Age categorical Units: Subjects			
65-74 years	7	4	6
75 years and over	3	3	4
Gender categorical Units: Subjects			
Female	4	3	3
Male	6	4	7
Ethnicity Units: Subjects			
White British	10	6	10
Indian	0	1	0
flu vaccination Units: Subjects			
yes	5	3	5
no	5	4	5
pneumonia vaccination Units: Subjects			
yes	4	0	2
no	6	7	8
Shingles Vaccination Units: Subjects			
yes	0	0	0
no	10	7	10
BMI Units: BMI (kg/m2)			
arithmetic mean	28.2	27.5	27.1
standard deviation	± 3.8	± 4.0	± 3
EQ-5D-Dl score Units: score			

arithmetic mean	0.92	0.96	0.9
standard deviation	± 0.07	± 0.05	± 0.09
SF36 physical component score			
physical component score			
Units: score			
arithmetic mean	44.6	46.7	47.7
standard deviation	± 13.5	± 3.4	± 5.5
SF36 (mental component score)			
mental component score			
Units: score			
arithmetic mean	60.9	59.7	61.7
standard deviation	± 4.2	± 5.0	± 3.1

Reporting group values	valaciclovir 1000mg q.d.s.	Total	
Number of subjects	11	38	
Age categorical			
Units: Subjects			
65-74 years	7	24	
75 years and over	4	14	
Gender categorical			
Units: Subjects			
Female	6	16	
Male	5	22	
Ethnicity			
Units: Subjects			
White British	11	37	
Indian	0	1	
flu vaccination			
Units: Subjects			
yes	2	15	
no	9	23	
pneumonia vaccination			
Units: Subjects			
yes	1	7	
no	10	31	
Shingles Vaccination			
Units: Subjects			
yes	0	0	
no	11	38	
BMI			
Units: BMI (kg/m2)			
arithmetic mean	25.8		
standard deviation	± 4.3	-	
EQ-5D-Dl score			
Units: score			
arithmetic mean	0.89		
standard deviation	± 0.14	-	
SF36 physical component score			
physical component score			
Units: score			
arithmetic mean	42.9		

standard deviation	± 15.8	-	
SF36 (mental component score)			
mental component score			
Units: score			
arithmetic mean	58.8		
standard deviation	± 6.7	-	

End points

End points reporting groups	
Reporting group title	no treatment
Reporting group description: no treatment	
Reporting group title	valaciclovir 500mg b.d.
Reporting group description: 500mg Valaciclovir twice a day	
Reporting group title	valaciclovir 1000mg b.d.
Reporting group description: 1000mg Valaciclovir twice a day	
Reporting group title	valaciclovir 1000mg q.d.s.
Reporting group description: 1000mg Valaciclovir four times a day	

Primary: CD4+ CMV-specific response	
End point title	CD4+ CMV-specific response
End point description: results shown as a geometric mean ratio compared to no treatment	
End point type	Primary
End point timeframe: on treatment period, i.e. the first 6 months	

End point values	no treatment	valaciclovir 500mg b.d.	valaciclovir 1000mg b.d.	valaciclovir 1000mg q.d.s.
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	10	11
Units: % lymphocytes				
geometric mean (confidence interval 95%)	0.44 (0.35 to 0.56)	0.62 (0.43 to 0.91)	1.15 (0.82 to 1.62)	0.82 (0.59 to 1.14)

Statistical analyses

Statistical analysis title	Primary outcome analysis
Statistical analysis description: CD4+ CMV-specific response	
Comparison groups	no treatment v valaciclovir 500mg b.d. v valaciclovir 1000mg b.d. v valaciclovir 1000mg q.d.s.

Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Mixed models analysis

Primary: CD8+ Tetramer+ response

End point title	CD8+ Tetramer+ response

End point description:

End point type	Primary

End point timeframe:

on treatment period, i.e. the first 6 months

End point values	no treatment	valaciclovir 500mg b.d.	valaciclovir 1000mg b.d.	valaciclovir 1000mg q.d.s.
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	10	11
Units: % lymphocytes				
geometric mean (confidence interval 95%)	2.11 (1.59 to 2.80)	0.92 (0.59 to 1.43)	1.01 (0.70 to 1.47)	1.1 (0.73 to 1.66)

Statistical analyses

Statistical analysis title	Primary outcome analysis

Statistical analysis description:

CD8+ Tetramer+ response

Comparison groups	valaciclovir 500mg b.d. v valaciclovir 1000mg b.d. v no treatment v valaciclovir 1000mg q.d.s.
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Mixed models analysis

Primary: CMV IgG titre

End point title	CMV IgG titre

End point description:

results shown as a geometric mean ratio compared to no treatment

End point type	Primary

End point timeframe:

on treatment period, i.e. the first 6 months

End point values	no treatment	valaciclovir 500mg b.d.	valaciclovir 1000mg b.d.	valaciclovir 1000mg q.d.s.
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	10	11
Units: units				
geometric mean (confidence interval 95%)	181.6 (148.7 to 221.7)	1.11 (0.81 to 1.52)	0.91 (0.69 to 1.20)	1.0 (0.76 to 1.32)

Statistical analyses

Statistical analysis title	primary end point analysis
Comparison groups	no treatment v valaciclovir 500mg b.d. v valaciclovir 1000mg b.d. v valaciclovir 1000mg q.d.s.
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Mixed models analysis

Secondary: CD4+ CD28- whole blood count (cells/µl)

End point title	CD4+ CD28- whole blood count (cells/µl)
End point description: results shown as a geometric mean ratio compared to no treatment	
End point type	Secondary
End point timeframe: on treatment period, i.e. the first 6 months	

End point values	no treatment	valaciclovir 500mg b.d.	valaciclovir 1000mg b.d.	valaciclovir 1000mg q.d.s.
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	10	11
Units: cells/µl				
geometric mean (confidence interval 95%)	23.8 (19.3 to 29.2)	1.22 (0.89 to 1.69)	0.99 (0.74 to 1.32)	1.08 (0.81 to 1.44)

Statistical analyses

No statistical analyses for this end point

Secondary: CD8+ CD28- whole blood count (cells/µl)

End point title	CD8+ CD28- whole blood count (cells/µl)

End point description:

results shown as a geometric mean ratio compared to no treatment

End point type	Secondary

End point timeframe:

on treatment period, i.e. the first 6 months

End point values	no treatment	valaciclovir 500mg b.d.	valaciclovir 1000mg b.d.	valaciclovir 1000mg q.d.s.
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	10	11
Units: (cells/µl)				
geometric mean (confidence interval 95%)	147.6 (122.7 to 177.4)	1.44 (1.08 to 1.92)	1.09 (0.84 to 1.41)	1.17 (0.9 to 1.5)

Statistical analyses

No statistical analyses for this end point

Secondary: SF36 physical component score

End point title	SF36 physical component score

End point description:

results shown as a difference compared to no treatment

End point type	Secondary

End point timeframe:

on treatment period, i.e. the first 6 months

End point values	no treatment	valaciclovir 500mg b.d.	valaciclovir 1000mg b.d.	valaciclovir 1000mg q.d.s.
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	10	11
Units: score				
geometric mean (confidence interval 95%)	45.0 (42.4 to 47.7)	0.65 (-3.54 to 4.84)	2.28 (-2.08 to 6.65)	-0.38 (-4.13 to 3.38)

Statistical analyses

No statistical analyses for this end point

Secondary: SF36 mental component score

End point title	SF36 mental component score

End point description:

results shown as a difference compared to no treatment

End point type	Secondary

End point timeframe:

on treatment period, i.e. the first 6 months

End point values	no treatment	valaciclovir 500mg b.d.	valaciclovir 1000mg b.d.	valaciclovir 1000mg q.d.s.
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	10	11
Units: score				
geometric mean (confidence interval 95%)	59.6 (57.6 to 61.5)	-0.60 (-3.65 to 2.45)	-0.04 (-3.23 to 3.15)	-0.78 (-3.52 to 1.97)

Statistical analyses

No statistical analyses for this end point

Secondary: EQ-5D-5L score

End point title	EQ-5D-5L score

End point description:

results shown as a difference compared to no treatment

End point type	Secondary

End point timeframe:

on treatment period, i.e. the first 6 months

End point values	no treatment	valaciclovir 500mg b.d.	valaciclovir 1000mg b.d.	valaciclovir 1000mg q.d.s.
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	10	11
Units: score				
geometric mean (confidence interval 95%)	0.89 (0.87 to 0.92)	0.01 (-0.03 to 0.05)	0.05 (0.01 to 0.08)	0.008 (-0.03 to 0.05)

Statistical analyses

No statistical analyses for this end point

Secondary: Haemoglobin

End point title	Haemoglobin

End point description:

results shown as a difference compared to no treatment

End point type	Secondary

End point timeframe:

on treatment period, i.e. the first 6 months

End point values	no treatment	valaciclovir 500mg b.d.	valaciclovir 1000mg b.d.	valaciclovir 1000mg q.d.s.
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	10	11
Units: g/l				
geometric mean (confidence interval 95%)	137.6 (134.5 to 140.7)	2.17 (-2.91 to 7.25)	1.29 (-3.10 to 5.67)	0.43 (-3.88 to 4.74)

Statistical analyses

No statistical analyses for this end point

Secondary: White blood cell count

End point title	White blood cell count

End point description:

End point type	Secondary

End point timeframe:

on treatment period, i.e. the first 6 months

End point values	no treatment	valaciclovir 500mg b.d.	valaciclovir 1000mg b.d.	valaciclovir 1000mg q.d.s.
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	10	11
Units: Cells x10 9/l				
geometric mean (confidence interval 95%)	6.3 (5.7 to 6.9)	0.55 (-0.37 to 1.47)	-0.09 (-0.88 to 0.71)	-0.52 (-1.3 to 0.26)

Statistical analyses

No statistical analyses for this end point

Secondary: neutrophils

End point title	neutrophils

End point description:

End point type	Secondary

End point timeframe:
on treatment period, i.e. the first 6 months

End point values	no treatment	valaciclovir 500mg b.d.	valaciclovir 1000mg b.d.	valaciclovir 1000mg q.d.s.
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	10	11
Units: cells x10 9/l				
geometric mean (confidence interval 95%)	3.7 (3.2 to 4.2)	0.52 (-0.23 to 1.27)	0.06 (-0.6 to 0.71)	-0.35 (-1.0 to 0.29)

Statistical analyses

No statistical analyses for this end point

Secondary: Platelets

End point title	Platelets

End point description:

End point type	Secondary

End point timeframe:
on treatment period, i.e. the first 6 months

End point values	no treatment	valaciclovir 500mg b.d.	valaciclovir 1000mg b.d.	valaciclovir 1000mg q.d.s.
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	10	11
Units: cells x10 9/l				
geometric mean (confidence interval 95%)	223.5 (210.4 to 236.5)	-0.99 (-22.28 to 0.29)	5.13 (-13.77 to 14.04)	6.8 (-11.16 to 14.76)

Statistical analyses

No statistical analyses for this end point

Secondary: lymphocytes

End point title	lymphocytes

End point description:

End point type	Secondary

End point timeframe:
on treatment period, i.e. the first 6 months

End point values	no treatment	valaciclovir 500mg b.d.	valaciclovir 1000mg b.d.	valaciclovir 1000mg q.d.s.
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	10	11
Units: cells x 10 9/l				
geometric mean (confidence interval 95%)	1.8 (1.7 to 2.0)	-0.06 (-0.31 to 0.18)	-0.11 (-0.33 to 0.10)	0.001 (-0.21 to 0.21)

Statistical analyses

No statistical analyses for this end point

Secondary: mean corpuscular volume (MCV)

End point title	mean corpuscular volume (MCV)

End point description:

End point type	Secondary

End point timeframe:

on treatment period, i.e. the first 6 months

End point values	no treatment	valaciclovir 500mg b.d.	valaciclovir 1000mg b.d.	valaciclovir 1000mg q.d.s.
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	10	11
Units: fl				
geometric mean (confidence interval 95%)	93.2 (91.4 to 95.0)	2.73 (-0.04 to 5.51)	4.64 (2.08 to 7.2)	7.66 (5.07 to 10.25)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: from randomisation up until 12 months (6 months post treatment)	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	14.2

Reporting groups	
Reporting group title	no treatment
Reporting group description: no treatment	
Reporting group title	valaciclovir 500mg b.d.
Reporting group description: 500mg Valaciclovir twice a day	
Reporting group title	valaciclovir 1000mg b.d.
Reporting group description: 1000mg Valaciclovir twice a day	
Reporting group title	valaciclovir 1000mg q.d.s.
Reporting group description: 1000mg Valaciclovir four times a day	

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 no non-serious adverse events that occurred at a frequency of >5%, therefore there are no events to be reported.

Serious adverse events	no treatment	valaciclovir 500mg b.d.	valaciclovir 1000mg b.d.
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	2 / 10 (20.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Cardiac disorders			
chest pain	Additional description: Chest Pain, Admitted to A&E for further investigation.		
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
raised HbA,c			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			

Admitted to Hospital following a fall			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
hallucinate	Additional description: hallucinated Admitted him to hospital. In hospital was diagnosed with pneumonia and septicemia following blood test and discharged 7 days later		
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	valaciclovir 1000mg q.d.s.		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 11 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Cardiac disorders			
chest pain	Additional description: Chest Pain, Admitted to A&E for further investigation.		
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
raised HbA,c			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Social circumstances			
Admitted to Hospital following a fall			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
hallucinate	Additional description: hallucinated Admitted him to hospital. In hospital was diagnosed with pneumonia and septicemia following blood test and discharged 7 days later		
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	no treatment	valaciclovir 500mg b.d.	valaciclovir 1000mg b.d.
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 10 (0.00%)

Non-serious adverse events	valaciclovir 1000mg q.d.s.		
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 11 (0.00%)		

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

baseline characteristics have only been included for those who completed the trial

Notes: