Clinical trial results:
A 26-week, multi-center, open-label study to investigate the efficacy and safety of CDP870 in active Crohn's disease patients, who showed clinical
efficacy in a remission induction study (Study C87037), at Week 26 after subcutaneous administration of CDP870 400 mg from Week 8 until Week 24 at 4-week intervals

Summary

EudraCT number	2014-004354-34
Trial protocol	Outside EU/EEA
Global end of trial date	08 April 2008

Results information

Result version number	v1 (current)
This version publication date	28 June 2016
First version publication date	17 June 2015

Trial information

Trial identification

Sponsor protocol code	C87047

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00329550
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UCB Japan Co., Ltd.
Sponsor organisation address	8-17-1 Nishi-Shinjuku, Tokyo, Japan, 160-0023
Public contact	Clinical Trial Registries and Results Disclosure, UCB BIOSCIENCES GmbH, +49 2173 4815 15, clinicaltrials@ucb.com
Scientific contact	Clinical Trial Registries and Results Disclosure, UCB BIOSCIENCES GmbH, +49 2173 48 15 15, clinicaltrials@ucb.com

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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	26 June 2008
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	08 April 2008
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 evaluate the efficacy of certolizumab pegol 400 mg administered subcutaneously (sc) at 4-week intervals from Week 8 to Week 24 in active Crohn's Disease (CD) subjects showing clinical efficacy at Week 6 of the induction study (Study C87037 [2014-004399-42]).

Protection of trial subjects:

Not applicable

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

Actual start date of recruitment	10 May 2006
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	Japan: 40
Worldwide total number of subjects	40
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)	5

Adults (18-64 years)	35
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment into this extension study was between March 2006 and April 2008. Of the 26 hospitals and medical centers throughout Japan in the main study, 16 sites went on to enter subjects in this extension study.

Pre-assignment

Screening details:

To enter this single-group extension study, C87047 (NCT00329550), subjects had to have responded at Week 6 of the double-blind main study, C87037 (NCT00291668). Recruitment details are provided for the 40 subjects who entered this extension study by the three possible treatment sequences received across both studies.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	CZP 400 mg / Placebo

Arm description:

Certolizumab pegol (CZP) 400 mg (5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (NCT00291668)

Arm type	Experimental
Investigational medicinal product name	Certolizumab Pegol
Investigational medicinal product code	CDP870
Other name	Cimzia
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Certolizumab pegol (CZP) 400 mg (5 doses 4-weekly) in this extension study.

Arm title	CZP 400 mg / CZP 200 mg

Arm description:

Certolizumab pegol (CZP) 400 mg (5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 200 mg (3 doses 2-weekly) in the 6-week double-blind main study (NCT00291668)

Arm type	Experimental
Investigational medicinal product name	Certolizumab Pegol
Investigational medicinal product code	CDP870
Other name	Cimzia
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Certolizumab pegol (CZP) 400 mg (5 doses 4-weekly) in this extension study.

Arm title	CZP 400 mg / CZP 400 mg

Arm description:

Certolizumab pegol (CZP) 400 mg (5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly) in the 6-week double-blind main study (NCT00291668)

Arm type	Experimental

Investigational medicinal product name	Certolizumab Pegol
Investigational medicinal product code	CDP870
Other name	Cimzia
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Certolizumab pegol (CZP) 400 mg (5 doses 4-weekly) in this extension study.

Number of subjects in period 1	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg
Started	9	15	16
Completed	5	11	12
Not completed	4	4	4
Consent withdrawn by subject	1	-	1
AE, non-serious non-fatal	1	1	-
Due to Relocation	-	-	1
SAE, non-fatal	2	3	2

Baseline characteristics

Reporting groups	
Reporting group title	CZP 400 mg / Placebo
Reporting group description:	
Certolizumab pegol (CZP) 400 mg (5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (NCT00291668)	
Reporting group title	CZP 400 mg / CZP 200 mg
Reporting group description:	
Certolizumab pegol (CZP) 400 mg (5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 200 mg (3 doses 2-weekly) in the 6-week double-blind main study (NCT00291668)	
Reporting group title	CZP 400 mg / CZP 400 mg
Reporting group description:	
Certolizumab pegol (CZP) 400 mg (5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly) in the 6-week double-blind main study (NCT00291668)	

Reporting group values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg
Number of subjects	9	15	16
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	1	2	2
Adults (18-64 years)	8	13	14
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	32.7	29.3	33.3
standard deviation	± 10.4	± 9.1	± 10
Gender Categorical Units: Subjects			
Female	2	3	4
Male	7	12	12
Region of Enrollment Units: Subjects			
Japan	9	15	16

Reporting group values	Total		
Number of subjects	40		
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)	5		
Adults (18-64 years)	35		
From 65-84 years	0		
85 years and over	0		
Age Continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender Categorical			
Units: Subjects			
Female	9		
Male	31		
Region of Enrollment			
Units: Subjects			
Japan	40		

End points

End points reporting groups

Reporting group title	CZP 400 mg / Placebo
Reporting group description:	
Certolizumab pegol (CZP) 400 mg (5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (NCT00291668)	
Reporting group title	CZP 400 mg / CZP 200 mg
Reporting group description:	
Certolizumab pegol (CZP) 400 mg (5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 200 mg (3 doses 2-weekly) in the 6-week double-blind main study (NCT00291668)	
Reporting group title	CZP 400 mg / CZP 400 mg
Reporting group description:	
Certolizumab pegol (CZP) 400 mg (5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly) in the 6-week double-blind main study (NCT00291668)	

Primary: Percentage of Crohn’s Disease Activity Index (CDAI) responders at Week 26

End point title	Percentage of Crohn’s Disease Activity Index (CDAI) responders at Week 26[1]
End point description:	
CDAI responders are subjects achieving either clinical response (a reduction in CDAI score of ≥100 points from Week 0), or remission (CDAI ≤150). CDAI is used to quantify the symptoms of subjects with Crohn’s disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.	
End point type	Primary
End point timeframe:	
Week 0 and Week 26 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 26' is 18 weeks after the first visit in this extension study.	

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: No formal statistical hypothesis testing was planned for this study. Results were summarized in tables as descriptive statistics only.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of CDAI responders	44.4	73.3	60	
Percentage of CDAI non-responders	55.6	26.7	40	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn’s Disease Activity Index (CDAI) Score at Week 8

End point title	Change from Week 0 in Crohn’s Disease Activity Index (CDAI) Score at Week 8

End point description:

CDAI is used to quantify the symptoms of subjects with Crohn’s disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

End point type	Secondary

End point timeframe:

Week 0 and Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-126.7 (± 100.9)	-124.9 (± 76.7)	-141.8 (± 62.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn’s Disease Activity Index (CDAI) Score at Week 12

End point title	Change from Week 0 in Crohn’s Disease Activity Index (CDAI) Score at Week 12

End point description:

CDAI is used to quantify the symptoms of subjects with Crohn’s disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

End point type	Secondary

End point timeframe:

Week 0 and Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	14	15	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-152.6 (± 96.8)	-145.4 (± 80.5)	-152.8 (± 54.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn’s Disease Activity Index (CDAI) Score at Week 16

End point title	Change from Week 0 in Crohn’s Disease Activity Index (CDAI) Score at Week 16

End point description:

CDAI is used to quantify the symptoms of subjects with Crohn’s disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

End point type	Secondary

End point timeframe:

Week 0 and Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	13	14	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-162.8 (± 98.9)	-142.2 (± 84.3)	-143.3 (± 69.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 20

End point title	Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 20

End point description:

CDAI is used to quantify the symptoms of subjects with Crohn’s disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

End point type	Secondary

End point timeframe:

Week 0 and Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	12	14	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-147 (± 38.8)	-149.4 (± 85.6)	-130.7 (± 70.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn’s Disease Activity Index (CDAI) Score at Week 24

End point title	Change from Week 0 in Crohn’s Disease Activity Index (CDAI) Score at Week 24

End point description:

CDAI is used to quantify the symptoms of subjects with Crohn’s disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

End point type	Secondary

End point timeframe:

Week 0 and Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	11	13	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-158.6 (± 53.7)	-153.3 (± 53.7)	-138.9 (± 80)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn’s Disease Activity Index (CDAI) Score at Week 26

End point title	Change from Week 0 in Crohn’s Disease Activity Index (CDAI) Score at Week 26

End point description:

CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

End point type	Secondary

End point timeframe:

Week 0 and Week 26 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	11	12	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-131.1 (± 32.8)	-173.8 (± 46.5)	-153.1 (± 70.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Last Visit [Week 26 for completers or the Withdrawal Visit for premature withdrawals]

End point title	Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Last Visit [Week 26 for completers or the Withdrawal Visit for premature withdrawals]

End point description:

CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

End point type	Secondary

End point timeframe:

Week 0 and Last Visit (Week 26 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	13	13	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-132.7 (± 62.6)	-143.2 (± 88.5)	-152.5 (± 67.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 8

End point title	Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 8

End point description:

CDAI responders are subjects achieving either clinical response (a reduction in CDAI score of ≥100 points from Week 0), or remission (CDAI ≤150). CDAI is used to quantify the symptoms of subjects with Crohn’s disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

End point type	Secondary

End point timeframe:

Week 0 and Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of CDAI responders	55.6	66.7	80	
Percentage of CDAI non-responders	44.4	33.3	20	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 12

End point title	Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 12

End point description:

CDAI responders are subjects achieving either clinical response (a reduction in CDAI score of ≥100 points from Week 0), or remission (CDAI ≤150). CDAI is used to quantify the symptoms of subjects with Crohn’s disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

End point type	Secondary

End point timeframe:

Week 0 and Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)).

'Week 12' is 4 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of CDAI responders	77.8	73.3	86.7	
Percentage of CDAI non-responders	22.2	26.7	13.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 16

End point title	Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 16

End point description:

CDAI responders are subjects achieving either clinical response (a reduction in CDAI score of ≥100 points from Week 0), or remission (CDAI ≤150). CDAI is used to quantify the symptoms of subjects with Crohn’s disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

End point type	Secondary

End point timeframe:

Week 0 and Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of CDAI responders	77.8	60	66.7	
Percentage of CDAI non-responders	22.2	40	33.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at

Week 20

End point title	Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 20

End point description:

CDAI responders are subjects achieving either clinical response (a reduction in CDAI score of ≥100 points from Week 0), or remission (CDAI ≤150). CDAI is used to quantify the symptoms of subjects with Crohn’s disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

End point type	Secondary

End point timeframe:

Week 0 and Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of CDAI responders	66.7	60	60	
Percentage of CDAI non-responders	33.3	40	40	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 24

End point title	Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 24

End point description:

CDAI responders are subjects achieving either clinical response (a reduction in CDAI score of ≥100 points from Week 0), or remission (CDAI ≤150). CDAI is used to quantify the symptoms of subjects with Crohn’s disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

End point type	Secondary

End point timeframe:

Week 0 and Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of CDAI responders	44.4	60	53.3	

Percentage of CDAI non-responders	55.6	40	46.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Last Visit [Week 26 for completers or the Withdrawal Visit for premature withdrawals]

End point title	Percentage of Crohn's Disease Activity Index (CDAI) responders at Last Visit [Week 26 for completers or the Withdrawal Visit for premature withdrawals]

End point description:

CDAI responders are subjects achieving either clinical response (a reduction in CDAI score of ≥100 points from Week 0), or remission (CDAI ≤150). CDAI is used to quantify the symptoms of subjects with Crohn’s disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

End point type	Secondary

End point timeframe:

Week 0 and Last Visit (Week 26 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of CDAI responders	44.4	73.3	60	
Percentage of CDAI non-responders	55.6	26.7	40	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 8

End point title	Percentage of subjects achieving remission at Week 8

End point description:

The Crohn’s Disease Activity Index (CDAI) is used to quantify the symptoms of subjects with Crohn’s disease. A CDAI score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

End point type	Secondary

End point timeframe:

Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of subjects in remission	33.3	40	53.3	
Percentage of subjects not in remission	66.7	60	46.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 12

End point title	Percentage of subjects achieving remission at Week 12

End point description:

The Crohn’s Disease Activity Index (CDAI) is used to quantify the symptoms of subjects with Crohn’s disease. A CDAI score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

End point type	Secondary

End point timeframe:

Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of subjects in remission	44.4	46.7	53.3	
Percentage of subjects not in remission	55.6	53.3	46.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 16

End point title	Percentage of subjects achieving remission at Week 16

End point description:

The Crohn’s Disease Activity Index (CDAI) is used to quantify the symptoms of subjects with Crohn’s disease. A CDAI score of 150 or below indicates remission and a score above 450 indicates extremely

severe disease.

End point type	Secondary

End point timeframe:

Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of subjects in remission	44.4	46.7	40	
Percentage of subjects not in remission	55.6	53.3	60	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 20

End point title	Percentage of subjects achieving remission at Week 20

End point description:

The Crohn’s Disease Activity Index (CDAI) is used to quantify the symptoms of subjects with Crohn’s disease. A CDAI score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

End point type	Secondary

End point timeframe:

Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of subjects in remission	22.2	53.3	40	
Percentage of subjects not in remission	77.8	46.7	60	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 24

End point title	Percentage of subjects achieving remission at Week 24

End point description:

The Crohn’s Disease Activity Index (CDAI) is used to quantify the symptoms of subjects with Crohn’s disease. A CDAI score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

End point type	Secondary

End point timeframe:

Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of subjects in remission	22.2	46.7	40	
Percentage of subjects not in remission	77.8	53.3	60	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 26

End point title	Percentage of subjects achieving remission at Week 26

End point description:

The Crohn’s Disease Activity Index (CDAI) is used to quantify the symptoms of subjects with Crohn’s disease. A CDAI score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

End point type	Secondary

End point timeframe:

Week 26 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of subjects in remission	22.2	46.7	46.7	
Percentage of subjects not in remission	77.8	53.3	53.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Last Visit (Week 26 for completers or the Withdrawal Visit for premature withdrawals)

End point title	Percentage of subjects achieving remission at Last Visit (Week 26 for completers or the Withdrawal Visit for premature withdrawals)

End point description:

The Crohn's Disease Activity Index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A CDAI score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

End point type	Secondary

End point timeframe:

Last Visit (Week 26 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of subjects in remission	22.2	46.7	46.7	
Percentage of subjects not in remission	77.8	53.3	53.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to disease progression

End point title	Time to disease progression

End point description:

Time to disease progression is defined as the earliest of:
- time to an increase from Week 6 of ≥100 points in Crohn's Disease Activity Index (CDAI) score and CDAI >175 points for at least 2 consecutive visits,
- time to use of rescue therapy, or,
- time to subject withdrawal from the study.

End point type	Secondary

End point timeframe:

Week 6 to Week 26 (relative to the start of the 6-week double-blind main study (NCT00291668)).

'Week 6' is the last visit in the double-blind main study and 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[2]	0[3]	0[4]	
Units: days				
median (confidence interval 95%)	(to)	(to)	(to)	

Notes:

[2] - Less than 50 % of subjects had their disease progress by Week 26. This analysis was not performed.
[3] - Less than 50 % of subjects had their disease progress by Week 26. This analysis was not performed.
[4] - Less than 50 % of subjects had their disease progress by Week 26. This analysis was not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 8 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score

End point title	Change from Week 0 to Week 8 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score

End point description:

The IBDQ Global Score is the sum of 32 responses, each ranging from 0 to 7, thus the Global Score ranges from 0 to 224; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	33.8 (± 25.6)	30.4 (± 25.8)	23.7 (± 20.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 12 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score

End point title	Change from Week 0 to Week 12 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score

End point description:

The IBDQ Global Score is the sum of 32 responses, each ranging from 0 to 7, thus the Global Score ranges from 0 to 224; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	14	15	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	37.6 (± 27)	29.9 (± 28.6)	25.5 (± 20.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 16 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score

End point title	Change from Week 0 to Week 16 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score

End point description:

The IBDQ Global Score is the sum of 32 responses, each ranging from 0 to 7, thus the Global Score ranges from 0 to 224; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	13	14	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	31 (± 31.6)	30.1 (± 25.4)	22.6 (± 22.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 20 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score

End point title	Change from Week 0 to Week 20 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score

End point description:

The IBDQ Global Score is the sum of 32 responses, each ranging from 0 to 7, thus the Global Score ranges from 0 to 224; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	12	14	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	32.2 (± 20.7)	31.6 (± 27.6)	19.2 (± 25.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 24 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score

End point title	Change from Week 0 to Week 24 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score

End point description:

The IBDQ Global Score is the sum of 32 responses, each ranging from 0 to 7, thus the Global Score ranges from 0 to 224; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	11	13	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	34 (± 13.4)	32.7 (± 24.6)	23.6 (± 22.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 26 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score

End point title	Change from Week 0 to Week 26 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score

End point description:

The IBDQ Global Score is the sum of 32 responses, each ranging from 0 to 7, thus the Global Score ranges from 0 to 224; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 26 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	11	12	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	33.4 (± 17)	38.4 (± 27)	28.2 (± 19.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Last Visit (Week 26 for completers or the Withdrawal Visit for premature withdrawals) in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score

End point title	Change from Week 0 to Last Visit (Week 26 for completers or the Withdrawal Visit for premature withdrawals) in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score

End point description:

The Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score is the sum of 32 responses, each ranging from 0 to 7, thus the Global Score ranges from 0 to 224; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Last Visit (Week 26 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	13	13	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	28 (± 21.5)	33.3 (± 27.7)	26.1 (± 20.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 8 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score

End point title	Change from Week 0 to Week 8 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score

End point description:

The IBDQ Bowel Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	10.7 (± 5.8)	10.3 (± 8.6)	9.5 (± 10.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 12 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score

End point title	Change from Week 0 to Week 12 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score

End point description:

The IBDQ Bowel Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	14	15	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	12.6 (± 6.9)	10.2 (± 10.8)	9.8 (± 8.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 16 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score

End point title	Change from Week 0 to Week 16 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score

End point description:

The IBDQ Bowel Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	13	14	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	9.9 (± 8.3)	8.8 (± 9.6)	6.7 (± 7.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 20 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score

End point title	Change from Week 0 to Week 20 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score

End point description:

The IBDQ Bowel Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	12	14	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	9.5 (± 8.3)	11.3 (± 9.7)	6.7 (± 8.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 24 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score

End point title	Change from Week 0 to Week 24 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score

End point description:

The IBDQ Bowel Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	11	13	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	11 (± 3)	10.4 (± 8.7)	8 (± 9.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 26 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score

End point title	Change from Week 0 to Week 26 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score

End point description:

The IBDQ Bowel Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 26 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	11	12	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	11.6 (± 4.2)	12 (± 10.4)	8.8 (± 9.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Last Visit (Week 26 for completers or the Withdrawal Visit for premature withdrawals) in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score

End point title	Change from Week 0 to Last Visit (Week 26 for completers or the Withdrawal Visit for premature withdrawals) in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score

End point description:

The Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Last Visit (Week 26 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	13	13	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	9.6 (± 5.8)	10.7 (± 10.1)	8.1 (± 9.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 8 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score

End point title	Change from Week 0 to Week 8 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score

End point description:

The IBDQ Systemic Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	7.6 (± 7)	7.1 (± 5.9)	5.7 (± 4.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 12 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score

End point title	Change from Week 0 to Week 12 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score

End point description:

The IBDQ Systemic Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	14	15	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	7.4 (± 7.8)	7.4 (± 6)	5.9 (± 5.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 16 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score

End point title	Change from Week 0 to Week 16 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score

End point description:

The IBDQ Systemic Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	13	14	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	6.8 (± 9.1)	7.9 (± 5.9)	5.9 (± 6.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 20 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score

End point title	Change from Week 0 to Week 20 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score

End point description:

The IBDQ Systemic Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	12	14	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	7.5 (± 3.4)	7.3 (± 6.6)	4.9 (± 6.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 24 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score

End point title	Change from Week 0 to Week 24 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score

End point description:

The IBDQ Systemic Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	11	13	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	8.2 (± 3.1)	7.5 (± 6.7)	6.2 (± 3.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 26 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score

End point title	Change from Week 0 to Week 26 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score

End point description:

The IBDQ Systemic Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 26 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	11	12	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	6.4 (± 3.5)	8.7 (± 5.6)	7.2 (± 3.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Last Visit (Week 26 for completers or the Withdrawal Visit for premature withdrawals) in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score

End point title	Change from Week 0 to Last Visit (Week 26 for completers or the Withdrawal Visit for premature withdrawals) in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score

End point description:

The Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Last Visit (Week 26 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	13	13	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	5.1 (± 6.8)	8.8 (± 5.1)	7.2 (± 3.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 8 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score

End point title	Change from Week 0 to Week 8 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score

End point description:

The IBDQ Emotional Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	9.4 (± 7)	7.5 (± 8.6)	5.1 (± 8.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 12 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score

End point title	Change from Week 0 to Week 12 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score

End point description:

The IBDQ Emotional Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	14	15	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	10.8 (± 7.6)	7.7 (± 8.2)	5.4 (± 9.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 16 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score

End point title	Change from Week 0 to Week 16 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score

End point description:

The IBDQ Emotional Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	13	14	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	8 (± 8.2)	7.8 (± 8.4)	6.1 (± 9.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 20 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score

End point title	Change from Week 0 to Week 20 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score

End point description:

The IBDQ Emotional Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	12	14	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	8.5 (± 9.4)	6.8 (± 9.4)	4.1 (± 10.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 24 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score

End point title	Change from Week 0 to Week 24 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score

End point description:

The IBDQ Emotional Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	11	13	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	8.3 (± 6.1)	8.6 (± 9.1)	6.2 (± 10.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 26 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score

End point title	Change from Week 0 to Week 26 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score

End point description:

The IBDQ Emotional Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 26 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	11	12	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	9.4 (± 7.2)	11.3 (± 11.1)	6.8 (± 8.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Last Visit (Week 26 for completers or the Withdrawal Visit for premature withdrawals) in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score

End point title	Change from Week 0 to Last Visit (Week 26 for completers or the Withdrawal Visit for premature withdrawals) in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score

End point description:

The Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Last Visit (Week 26 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	13	13	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	7.4 (± 6.8)	9 (± 11.6)	5.8 (± 9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 8 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score

End point title	Change from Week 0 to Week 8 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score

End point description:

The IBDQ Social Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	6.1 (± 7.4)	5.5 (± 7.1)	3.5 (± 4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 12 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score

End point title	Change from Week 0 to Week 12 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score

End point description:

The IBDQ Social Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	14	15	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	6.9 (± 7.9)	4.5 (± 8.9)	4.5 (± 4.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 16 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score

End point title	Change from Week 0 to Week 16 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score

End point description:

The IBDQ Social Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	13	14	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	6.4 (± 7.7)	5.6 (± 7.3)	4 (± 4.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 20 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score

End point title	Change from Week 0 to Week 20 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score

End point description:

The IBDQ Social Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	12	14	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	6.7 (± 5.8)	6.1 (± 7.9)	3.6 (± 5.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 24 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score

End point title	Change from Week 0 to Week 24 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score

End point description:

The IBDQ Social Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	11	13	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	6.5 (± 6.1)	6.2 (± 7.8)	3.3 (± 4.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Week 26 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score

End point title	Change from Week 0 to Week 26 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score

End point description:

The IBDQ Social Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Week 26 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	11	12	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	6 (± 5.8)	6.4 (± 7.8)	5.7 (± 5.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 to Last Visit (Week 26 for completers or the Withdrawal Visit for premature withdrawals) in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score

End point title	Change from Week 0 to Last Visit (Week 26 for completers or the Withdrawal Visit for premature withdrawals) in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score

End point description:

The Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

End point type	Secondary

End point timeframe:

Week 0 and Last Visit (Week 26 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	13	13	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	5.9 (± 6)	4.8 (± 8.5)	5.2 (± 5.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 0

End point title	C-Reactive Protein (CRP) Level at Week 0

End point description:

End point type	Secondary

End point timeframe:

Week 0 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 0' is the Baseline visit in the double-blind main study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: mg/L				
geometric mean (full range (min-max))				
mean (standard deviation)	21.37 (1 to 68)	26.31 (11 to 77)	25.88 (5 to 92)	

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 8

End point title	C-Reactive Protein (CRP) Level at Week 8

End point description:

End point type	Secondary

End point timeframe:

Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: mg/L				
geometric mean (full range (min-max))				
mean (standard deviation)	23.8 (6 to 67)	19.11 (1 to 115)	11.61 (5 to 67)	

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 12

End point title	C-Reactive Protein (CRP) Level at Week 12

End point description:

End point type	Secondary

End point timeframe:

Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	14	15	
Units: mg/L				
geometric mean (full range (min-max))				
Geometric mean (full range)	12.55 (1 to 38)	14.91 (1 to 100)	11.64 (4 to 56)	

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 16

End point title	C-Reactive Protein (CRP) Level at Week 16

End point description:

End point type	Secondary

End point timeframe:

Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	13	14	
Units: mg/L				
geometric mean (full range (min-max))				
Geometric mean (full range)	16.12 (1 to 58)	16.06 (1 to 99)	14.05 (5 to 76)	

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 20

End point title	C-Reactive Protein (CRP) Level at Week 20

End point description:

End point type	Secondary

End point timeframe:

Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	12	14	
Units: mg/L				
geometric mean (full range (min-max))				
Geometric mean (full range)	17.16 (0 to 47)	13.16 (3 to 73)	17.44 (4 to 63)	

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 24

End point title	C-Reactive Protein (CRP) Level at Week 24

End point description:

End point type	Secondary

End point timeframe:

Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	11	13	
Units: mg/L				
geometric mean (full range (min-max))				
Geometric mean (full range)	10.97 (1 to 40)	12.44 (1 to 77)	16.84 (5 to 87)	

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 26

End point title	C-Reactive Protein (CRP) Level at Week 26

End point description:

End point type	Secondary

End point timeframe:

Week 26 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	11	12	
Units: mg/L				
geometric mean (full range (min-max))				
Geometric mean (full range)	15.94 (0 to 48)	9.96 (2 to 43)	13.11 (4 to 78)	

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Last Visit (Week 26 for completers or the Withdrawal Visit for premature withdrawals)

End point title	C-Reactive Protein (CRP) Level at Last Visit (Week 26 for completers or the Withdrawal Visit for premature withdrawals)

End point description:

End point type	Secondary

End point timeframe:

Last Visit (Week 26 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	13	13	
Units: mg/L				
geometric mean (full range (min-max))				
Geometric mean (full range)	19.81 (0 to 48)	13.12 (2 to 81)	14.04 (4 to 78)	

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) Level at Week 8 to Week 0

End point title	Ratio of C-Reactive Protein (CRP) Level at Week 8 to Week 0

End point description:

End point type	Secondary

End point timeframe:

Week 0 and Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: ratio				
geometric mean (full range (min-max))				
Geometric mean (full range)	1.11 (0.5 to 6)	0.73 (0.1 to 5.6)	0.45 (0.1 to 1.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) Level at Week 12 to Week 0

End point title	Ratio of C-Reactive Protein (CRP) Level at Week 12 to Week 0

End point description:

End point type	Secondary

End point timeframe:

Week 0 and Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	14	15	
Units: ratio				
geometric mean (full range (min-max))				
Geometric mean (full range)	0.63 (0.2 to 1.4)	0.55 (0.1 to 1.7)	0.45 (0.1 to 1.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) Level at Week 16 to Week 0

End point title	Ratio of C-Reactive Protein (CRP) Level at Week 16 to Week 0

End point description:

End point type	Secondary

End point timeframe:

Week 0 and Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	13	14	
Units: ratio				
geometric mean (full range (min-max))				
Geometric mean (full range)	0.81 (0.2 to 1.9)	0.59 (0.1 to 1.9)	0.53 (0.3 to 2.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) Level at Week 20 to Week 0

End point title	Ratio of C-Reactive Protein (CRP) Level at Week 20 to Week 0

End point description:

End point type	Secondary

End point timeframe:

Week 0 and Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	12	14	
Units: ratio				
geometric mean (full range (min-max))				
Geometric mean (full range)	0.65 (0 to 1.4)	0.53 (0.1 to 1.9)	0.66 (0.1 to 2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) Level at Week 24 to Week 0

End point title	Ratio of C-Reactive Protein (CRP) Level at Week 24 to Week 0

End point description:

End point type	Secondary

End point timeframe:

Week 0 and Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	11	13	
Units: ratio				
geometric mean (full range (min-max))				
Geometric mean (full range)	0.72 (0.2 to 1.8)	0.5 (0.1 to 1.7)	0.62 (0.1 to 1.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) Level at Week 26 to Week 0

End point title	Ratio of C-Reactive Protein (CRP) Level at Week 26 to Week 0

End point description:

End point type	Secondary

End point timeframe:

Week 0 and Week 26 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	11	12	
Units: ratio				
geometric mean (full range (min-max))				
Geometric mean (full range)	0.63 (0 to 1.2)	0.4 (0.1 to 1.7)	0.47 (0.1 to 2.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) Level at Last Visit (Week 26 for completers or the Withdrawal Visit for premature withdrawals) to Week 0

End point title	Ratio of C-Reactive Protein (CRP) Level at Last Visit (Week 26 for completers or the Withdrawal Visit for premature withdrawals) to Week 0

End point description:

End point type	Secondary

End point timeframe:

Week 0 and Last Visit (Week 26 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	13	13	
Units: ratio				
geometric mean (full range (min-max))				
Geometric mean (full range)	0.72 (0 to 1.2)	0.48 (0.1 to 1.8)	0.52 (0.1 to 2.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects at Week 8 achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0

End point title	Percentage of subjects at Week 8 achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0

End point description:

CDAI is used to quantify the symptoms of subjects with Crohn’s disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

End point type	Secondary

End point timeframe:

Week 0 and Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of 70-point responders	77.8	73.3	86.7	
Percentage of 70-point non-responders	22.2	26.7	13.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects at Week 12 achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0

End point title	Percentage of subjects at Week 12 achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0

End point description:

CDAI is used to quantify the symptoms of subjects with Crohn’s disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

End point type	Secondary

End point timeframe:

Week 0 and Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of 70-point responders	77.8	80	93.3	
Percentage of 70-point non-responders	22.2	20	6.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects at Week 16 achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥70 points from Week 0

End point title	Percentage of subjects at Week 16 achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥70 points from Week 0

End point description:

CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

End point type	Secondary

End point timeframe:

Week 0 and Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of 70-point responders	77.8	66.7	66.7	
Percentage of 70-point non-responders	22.2	33.3	33.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects at Week 20 achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥70 points from Week 0

End point title	Percentage of subjects at Week 20 achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥70 points from Week 0

End point description:

CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

End point type	Secondary

End point timeframe:

Week 0 and Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of 70-point responders	66.7	60	73.3	
Percentage of 70-point non-responders	33.3	40	26.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects at Week 24 achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥70 points from Week 0

End point title	Percentage of subjects at Week 24 achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥70 points from Week 0

End point description:

CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

End point type	Secondary

End point timeframe:

Week 0 and Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of 70-point responders	55.6	66.7	60	
Percentage of 70-point non-responders	44.4	33.3	40	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects at Week 26 achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥70 points from Week 0

End point title	Percentage of subjects at Week 26 achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥70 points from Week 0

End point description:

CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below

indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

End point type	Secondary

End point timeframe:

Week 0 and Week 26 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of 70-point responders	55.6	73.3	73.3	
Percentage of 70-point non-responders	44.4	26.7	26.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects at Last Visit (Week 26 for completers or the Withdrawal Visit for premature withdrawals) achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥70 points from Week 0

End point title	Percentage of subjects at Last Visit (Week 26 for completers or the Withdrawal Visit for premature withdrawals) achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥70 points from Week 0

End point description:

CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

End point type	Secondary

End point timeframe:

Week 0 and Last Visit (Week 26 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: Percentage of subjects				
number (not applicable)				
Percentage of 70-point responders	55.6	73.3	73.3	
Percentage of 70-point non-responders	44.4	26.7	26.7	

Statistical analyses

No statistical analyses for this end point

Post-hoc: Number of subjects with disease progression

End point title	Number of subjects with disease progression

End point description:

Disease progression is defined as:
- an increase from Week 6 of ≥100 points in Crohn's Disease Activity Index (CDAI) score and CDAI >175 points for at least 2 consecutive visits,
- use of rescue therapy, or,
- subject withdrawal from the study.

End point type	Post-hoc

End point timeframe:

Week 6 to Week 26 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 6' is the last visit in the double-blind main study and 'Week 26' is 18 weeks after the first visit in this extension study.

End point values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	15	
Units: subjects				
Number of subjects	2	3	1	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse event data were collected from the day after the end of the double-blind main study up to and including 12 weeks following the last dose received in this extension study for each subject (i.e., up to 30 weeks).

Adverse event reporting additional description:

Adverse Events refer to the Safety Set, including all enrolled subjects who received study medication at least once.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	9.0

Reporting groups

Reporting group title	CZP 400 mg / Placebo

Reporting group description:

Certolizumab pegol (CZP) 400 mg (5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (NCT00291668)

Reporting group title	CZP 400 mg / CZP 400 mg

Reporting group description:

Certolizumab pegol (CZP) 400 mg (5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly) in the 6-week double-blind main study (NCT00291668)

Reporting group title	CZP 400 mg / CZP 200 mg

Reporting group description:

Certolizumab pegol (CZP) 400 mg (5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 200 mg (3 doses 2-weekly) in the 6-week double-blind main study (NCT00291668)

Serious adverse events	CZP 400 mg / Placebo	CZP 400 mg / CZP 400 mg	CZP 400 mg / CZP 200 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 9 (22.22%)	5 / 16 (31.25%)	5 / 15 (33.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	1 / 9 (11.11%)	3 / 16 (18.75%)	4 / 15 (26.67%)
occurrences causally related to treatment / all	1 / 1	2 / 3	3 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ileal perforation			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Suicidal ideation			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	CZP 400 mg / Placebo	CZP 400 mg / CZP 400 mg	CZP 400 mg / CZP 200 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 9 (88.89%)	15 / 16 (93.75%)	12 / 15 (80.00%)
General disorders and administration site conditions			
Feeling abnormal			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Generalised oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 16 (6.25%)	1 / 15 (6.67%)
occurrences (all)	1	1	2
Immune system disorders			

Drug hypersensitivity			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Seasonal allergy			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Hiccups			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Pharynx discomfort			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Neurosis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Investigations			
Antinuclear antibody increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Antinuclear antibody positive			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0

Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
DNA antibody positive			
subjects affected / exposed	2 / 9 (22.22%)	2 / 16 (12.50%)	1 / 15 (6.67%)
occurrences (all)	2	2	1
White blood cell count decreased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Procedural hypotension			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dysgeusia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Extrapyramidal disorder			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0

Headache			
subjects affected / exposed	0 / 9 (0.00%)	2 / 16 (12.50%)	1 / 15 (6.67%)
occurrences (all)	0	2	1
Hypoaesthesia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Tension headache			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Crohn's disease			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Glossitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	2 / 9 (22.22%)	0 / 16 (0.00%)	2 / 15 (13.33%)
occurrences (all)	2	0	2
Toothache			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	2 / 9 (22.22%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	2	1	0
Hepatobiliary disorders			

Cholecystitis acute			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Hepatic function abnormal			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Liver disorder			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Alopecia areata			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Dermatitis psoriasiform			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Eczema asteatotic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Eczema nummular			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 9 (0.00%)	2 / 16 (12.50%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0

Musculoskeletal stiffness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Myalgia intercostal			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Infections and infestations			
Candidiasis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Colitis pseudomembranous			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Dental caries			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Herpes zoster			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Infection			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	1 / 9 (11.11%)	2 / 16 (12.50%)	1 / 15 (6.67%)
occurrences (all)	1	2	1
Laryngopharyngitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 9 (22.22%)	10 / 16 (62.50%)	3 / 15 (20.00%)
occurrences (all)	4	12	4
Otitis externa			

subjects affected / exposed	0 / 9 (0.00%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Pharyngitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 16 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 16 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2

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.

Due to the small number of subjects in this study, the percentages of subjects with adverse events may be misleading.

Notes: