Clinical trial results:
A multi-center, open-label study to investigate the efficacy and safety of CDP870 in active Crohn's disease patients, who showed no clinical efficacy in a remission induction study (Study CDP870-037) but showed clinical efficacy after additional remission induction therapy was applied, at Week 26 after subcutaneous administration of CDP870 400mg from Week 8 until Week 24 at 4-week intervals

Summary

EudraCT number	2014-004400-30
Trial protocol	Outside EU/EEA
Global end of trial date	11 May 2008

Results information

Result version number	v1 (current)
This version publication date	28 June 2016
First version publication date	10 July 2015

Trial information

Trial identification

Sponsor protocol code	C87048

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00329420
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UCB Japan Co., Ltd.
Sponsor organisation address	2-2 Kanda Surugadai, Tokyo, Japan, 101-0062
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	27 August 2008
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	11 May 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 400mg in subjects with active CD who were non-responders in the induction study (Study CDP870-037), but who responded to a second induction with certolizumab pegol. Subjects underwent re-induction with certolizumab pegol 400mg administered every 2 weeks for 3 doses; subjects who responded to the second induction received certolizumab pegol 400mg administered every 4 weeks for 5 doses.

Protection of trial subjects:

Not applicable

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

Actual start date of recruitment	02 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: 46
Worldwide total number of subjects	46
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)	1
Adults (18-64 years)	45
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Non-responders at Week 6 of the double-blind main study, C87037 (2014-004399-42) could enter this single-group open-label extension study, C87048 (2014-004400-30). Recruitment into this extension study was between May 2006 and May 2008. Of the 26 hospitals in the main study C87037 16 sites went on to enter subjects into this extension study.

Pre-assignment

Screening details:

Subjects who responded to re-induction (Week 14 visit) in this extension study could enter the 4-weekly dosing phase. Efficacy data are based on these 26 subjects. However, adverse event data are based on all 46 subjects who entered this extension study. Data are presented by the three possible treatment sequences received across both studies.

Period 1

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

Arms

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

Arm description:

Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

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

Dosage and administration details:

Certolizumab pegol (CZP)400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

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

Dosage and administration details:

Certolizumab pegol (CZP)400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)
Certolizumab pegol (CZP)400 mg (3 doses 2-weekly then 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 (2014-004399-42)
Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 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 (2014-004399-42)

Arm title	CZP 400 mg / CZP 200 mg

Arm description:

Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 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 (2014-004399-42)

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

Dosage and administration details:

Certolizumab pegol (CZP)400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)
Certolizumab pegol (CZP)400 mg (3 doses 2-weekly then 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 (2014-004399-42)
Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 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 (2014-004399-42)

Arm title	CZP 400 mg / CZP 400 mg

Arm description:

Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 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 (2014-004399-42)

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

Dosage and administration details:

Certolizumab pegol (CZP)400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)
Certolizumab pegol (CZP)400 mg (3 doses 2-weekly then 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 (2014-004399-42)
Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 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 (2014-004399-42)

Number of subjects in period 1	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg
Started	18	13	15
Moved to maintenance period	12	7	7
Completed	8	5	6
Not completed	10	8	9
Withdrawal of Consent	1	-	1
Did not respond to re-induction	3	5	4
AE, non-serious non-fatal	2	-	1
SAE, non-fatal	1	1	2
Lack of efficacy	3	2	1

Baseline characteristics

Reporting groups	
Reporting group title	CZP 400 mg / Placebo
Reporting group description:	
Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)	
Reporting group title	CZP 400 mg / CZP 200 mg
Reporting group description:	
Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 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 (2014-004399-42)	
Reporting group title	CZP 400 mg / CZP 400 mg
Reporting group description:	
Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 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 (2014-004399-42)	

Reporting group values	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg
Number of subjects	18	13	15
Age Categorical Units: Subjects			
<=18 years	1	0	0
Between 18 and 65 years	17	13	15
>=65 years	0	0	0
Age Continuous Units: years			
arithmetic mean	30.4	37.5	29.9
standard deviation	± 7.5	± 8.2	± 5.9
Gender Categorical Units: Subjects			
Female	4	4	3
Male	14	9	12
Region of Enrollment Units: Subjects			
Japan	18	13	15

Reporting group values	Total		
Number of subjects	46		
Age Categorical Units: Subjects			
<=18 years	1		
Between 18 and 65 years	45		
>=65 years	0		
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		

Gender Categorical Units: Subjects			
Female	11		
Male	35		
Region of Enrollment Units: Subjects			
Japan	46		

End points

End points reporting groups

Reporting group title	CZP 400 mg / Placebo
Reporting group description:	
Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)	
Reporting group title	CZP 400 mg / CZP 200 mg
Reporting group description:	
Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 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 (2014-004399-42)	
Reporting group title	CZP 400 mg / CZP 400 mg
Reporting group description:	
Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 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 (2014-004399-42)	

Primary: Percentage of Crohn’s Disease Activity Index (CDAI) Responders at Week 34

End point title	Percentage of Crohn’s Disease Activity Index (CDAI) Responders at Week 34[1]
End point description:	
Crohn's disease activity index (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 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of CDAI responders	66.7	28.6	42.9	
Percentage of CDAI non-responders	33.3	71.4	57.1	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Crohn's disease activity index (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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-20.5 (± 81.6)	-53.1 (± 38.1)	-63.8 (± 26.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 10

End point title	Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 10

End point description:

Crohn's disease activity index (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 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-96.1 (± 76.1)	-100.3 (± 35.4)	-90 (± 18.2)	

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:

Crohn's disease activity index (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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-101.3 (± 56.6)	-100.5 (± 49.3)	-109.9 (± 36.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 14

End point title	Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 14

End point description:

Crohn's disease activity index (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 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-124.3 (± 50.4)	-131.7 (± 41.3)	-147 (± 45.2)	

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:

Crohn's disease activity index (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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-121 (± 57.7)	-70.4 (± 84.1)	-136.2 (± 32.2)	

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:

Crohn's disease activity index (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	11	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-105.3 (± 82.9)	-79.6 (± 60.9)	-130.9 (± 62.5)	

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:

Crohn's disease activity index (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	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-89.8 (± 79.8)	-70.6 (± 91.3)	-150.2 (± 48)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 28

End point title	Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 28

End point description:

Crohn's disease activity index (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 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 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	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-118.2 (± 62.6)	-67.3 (± 77.1)	-154.8 (± 74.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 32

End point title	Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 32

End point description:

Crohn's disease activity index (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 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 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	5	6	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-89 (± 88.3)	-77.3 (± 70.9)	-128.3 (± 75.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 34

End point title	Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 34

End point description:

Crohn's disease activity index (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 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 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	5	5	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-134.9 (± 39.3)	-97.4 (± 33.1)	-132.7 (± 89.7)	

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 34 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 34 for completers or the Withdrawal Visit for premature withdrawals)

End point description:

Crohn's disease activity index (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 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 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	11	6	5	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-112 (± 75.6)	-61 (± 93.7)	-132.7 (± 89.7)	

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:

Crohn's disease activity index (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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of CDAI responders	8.3	14.3	14.3	
Percentage of CDAI non-responders	91.7	85.7	85.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 10

End point title	Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 10

End point description:

Crohn's disease activity index (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 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of CDAI responders	41.7	71.4	42.9	
Percentage of CDAI non-responders	58.3	28.6	57.1	

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:

Crohn's disease activity index (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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of CDAI responders	50	71.4	57.1	
Percentage of CDAI non-responders	50	28.6	42.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 14

End point title	Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 14

End point description:

Crohn's disease activity index (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 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of CDAI responders	100	100	100	
Percentage of CDAI non-responders	0	0	0	

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:

Crohn's disease activity index (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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of CDAI responders	66.7	42.9	85.7	
Percentage of CDAI non-responders	33.3	57.1	14.3	

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:

Crohn's disease activity index (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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of CDAI responders	41.7	28.6	85.7	
Percentage of CDAI non-responders	58.3	71.4	14.3	

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:

Crohn's disease activity index (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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of CDAI responders	41.7	57.1	71.4	
Percentage of CDAI non-responders	58.3	42.9	28.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 28

End point title	Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 28

End point description:

Crohn's disease activity index (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 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of CDAI responders	50	28.6	57.1	
Percentage of CDAI non-responders	50	71.4	42.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 32

End point title	Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 32

End point description:

Crohn's disease activity index (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 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of CDAI responders	33.3	28.6	57.1	
Percentage of CDAI non-responders	66.7	71.4	42.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Last Visit (Week 34 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 34 for completers or the Withdrawal Visit for premature withdrawals)

End point description:

Crohn's disease activity index (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 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of CDAI responders	66.7	28.6	42.9	
Percentage of CDAI non-responders	33.3	71.4	57.1	

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:

Crohn's disease activity index (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 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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of subjects in remission	0	0	14.3	
Percentage of subjects not in remission	100	100	85.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 10

End point title	Percentage of subjects achieving remission at Week 10

End point description:

Crohn's disease activity index (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 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of subjects in remission	33.3	42.9	14.3	
Percentage of subjects not in remission	66.7	57.1	85.7	

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:

Crohn's disease activity index (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 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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of subjects in remission	25	42.9	42.9	
Percentage of subjects not in remission	75	57.1	57.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 14

End point title	Percentage of subjects achieving remission at Week 14

End point description:

Crohn's disease activity index (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 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of subjects in remission	66.7	71.4	71.4	
Percentage of subjects not in remission	33.3	28.6	28.6	

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:

Crohn's disease activity index (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 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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of subjects in remission	33.3	28.6	57.1	
Percentage of subjects not in remission	66.7	71.4	42.9	

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:

Crohn's disease activity index (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 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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of subjects in remission	33.3	28.6	57.1	
Percentage of subjects not in remission	66.7	71.4	42.9	

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:

Crohn's disease activity index (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 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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of subjects in remission	16.7	42.9	71.4	
Percentage of subjects not in remission	83.3	57.1	28.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 28

End point title	Percentage of subjects achieving remission at Week 28

End point description:

Crohn's disease activity index (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 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of subjects in remission	25	28.6	57.1	
Percentage of subjects not in remission	75	71.4	42.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 32

End point title	Percentage of subjects achieving remission at Week 32

End point description:

Crohn's disease activity index (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 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of subjects in remission	16.7	28.6	42.9	
Percentage of subjects not in remission	83.3	71.4	57.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 34

End point title	Percentage of subjects achieving remission at Week 34

End point description:

Crohn's disease activity index (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 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of subjects in remission	33.3	28.6	42.9	
Percentage of subjects not in remission	66.7	71.4	57.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

End point title	Percentage of subjects achieving remission at Last Visit (Week

	34 for completers or the Withdrawal Visit for premature withdrawals)

End point description:

Crohn's disease activity index (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:

Last Visit (Week 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 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	12	7	7	
Units: Percentage of subjects				
number (not applicable)				
Percentage of subjects in remission	33.3	28.6	42.9	
Percentage of subjects not in remission	66.7	71.4	57.1	

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 14 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 14 to Week 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is the visit at which response to re-induction is assessed and 'Week 34' is 26 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%)				
median (95% CI)	(to)	(to)	(to)	

Notes:

[2] - No data displayed because Outcome Measure has zero total participants analyzed.

[3] - No data displayed because Outcome Measure has zero total participants analyzed.

[4] - No data displayed because Outcome Measure has zero total participants analyzed.

Statistical analyses

No statistical analyses for this end point

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

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

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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	4.6 (± 15.3)	9.1 (± 7.5)	5.3 (± 13.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 10

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 10

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 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	17 (± 17.5)	20.9 (± 24.9)	15.1 (± 13.4)	

Statistical analyses

No statistical analyses for this end point

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

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

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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	17.3 (± 12)	26.3 (± 33.6)	20.1 (± 16.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 14

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 14

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 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	20.1 (± 12.3)	28.6 (± 22.9)	26.3 (± 16.1)	

Statistical analyses

No statistical analyses for this end point

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

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

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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	16.3 (± 12.2)	15.3 (± 19.1)	20 (± 16.4)	

Statistical analyses

No statistical analyses for this end point

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

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

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	11	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	12.2 (± 16)	18.4 (± 27.5)	15.9 (± 14.7)	

Statistical analyses

No statistical analyses for this end point

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

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

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	9	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	8.3 (± 14.5)	7.6 (± 23.3)	18.4 (± 18)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 28

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 28

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 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 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	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	14.9 (± 20)	11.4 (± 24.3)	15.9 (± 19.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 32

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 32

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 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 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	5	6	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	11.3 (± 17.8)	11.2 (± 21.7)	25.3 (± 17)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 34

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 34

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 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 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	5	5	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	21.6 (± 16.9)	14.8 (± 23.6)	20.6 (± 17.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

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 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 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	11	6	5	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	15.6 (± 19.5)	10.8 (± 23.3)	20.6 (± 17.6)	

Statistical analyses

No statistical analyses for this end point

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

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

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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	1.9 (± 7.5)	6.4 (± 5.6)	2.4 (± 5.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 10

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 10

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 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	6.2 (± 8.4)	10.6 (± 8.4)	5.9 (± 7.1)	

Statistical analyses

No statistical analyses for this end point

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

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

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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	5.7 (± 4.4)	11.7 (± 9.7)	7.4 (± 7.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 14

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 14

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 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	6.9 (± 5.6)	12.3 (± 9.3)	9.3 (± 7)	

Statistical analyses

No statistical analyses for this end point

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

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

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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	5.2 (± 6.3)	8.4 (± 9.9)	6.3 (± 7.2)	

Statistical analyses

No statistical analyses for this end point

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

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

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	11	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	3.5 (± 7.4)	9.9 (± 11.7)	5.1 (± 5.5)	

Statistical analyses

No statistical analyses for this end point

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

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

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	9	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	0.7 (± 5.3)	4.7 (± 11)	5.6 (± 8.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 28

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 28

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 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 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	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	4.6 (± 6)	8.3 (± 10)	5.4 (± 8.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 32

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 32

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 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 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	5	6	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	3.1 (± 6.7)	9.6 (± 11)	7.5 (± 5.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 34

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 34

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 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 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	5	5	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	7.1 (± 4.9)	11.8 (± 9.8)	5.8 (± 6.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

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 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 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	11	6	5	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	5.5 (± 6.9)	8.3 (± 12.2)	5.8 (± 6.5)	

Statistical analyses

No statistical analyses for this end point

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

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

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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	1.4 (± 3.4)	0.6 (± 1.7)	1.7 (± 1.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 10

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 10

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 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	4.6 (± 4.4)	3.7 (± 6.2)	3.9 (± 1.3)	

Statistical analyses

No statistical analyses for this end point

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

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

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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	5.7 (± 3.2)	5 (± 7.3)	5.1 (± 2.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 14

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 14

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 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	5.9 (± 3)	6.4 (± 4.3)	6.3 (± 3.1)	

Statistical analyses

No statistical analyses for this end point

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

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

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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	5.5 (± 2.4)	3.9 (± 3.7)	5.3 (± 3.5)	

Statistical analyses

No statistical analyses for this end point

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

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

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	11	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	3.6 (± 4)	3.6 (± 6.3)	3.6 (± 2.6)	

Statistical analyses

No statistical analyses for this end point

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

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

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	9	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	3.1 (± 2.9)	2.1 (± 5.9)	4.1 (± 2.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 28

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 28

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 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 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	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	3 (± 6.1)	3 (± 5.8)	4.4 (± 3.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 32

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 32

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 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 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	5	6	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	3.4 (± 4.3)	0.4 (± 3.1)	6.8 (± 3.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 34

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 34

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 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 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	5	5	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	5 (± 3.2)	3 (± 4.8)	5.4 (± 2.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

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 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 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	11	6	5	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	4.2 (± 4.1)	3.2 (± 4.4)	5.4 (± 2.1)	

Statistical analyses

No statistical analyses for this end point

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

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

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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	-0.3 (± 6.1)	2.1 (± 2.3)	0.4 (± 6.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 10

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 10

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 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	3.3 (± 4.7)	4.4 (± 9.7)	4.3 (± 5.9)	

Statistical analyses

No statistical analyses for this end point

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

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

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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	2.5 (± 5.5)	7 (± 13.8)	5.3 (± 6.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 14

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 14

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 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	3.8 (± 4)	7.1 (± 10.3)	6.7 (± 8)	

Statistical analyses

No statistical analyses for this end point

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

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

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	12	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	2.5 (± 5.8)	3 (± 6.2)	6 (± 8.1)	

Statistical analyses

No statistical analyses for this end point

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

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

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	11	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	1.9 (± 6.5)	3.4 (± 10.7)	3.6 (± 6.9)	

Statistical analyses

No statistical analyses for this end point

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

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

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	9	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	2.1 (± 5.9)	1.6 (± 5.7)	6.1 (± 7.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 28

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 28

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 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 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	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	4.3 (± 5.8)	1.1 (± 8)	3.6 (± 7.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 32

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 32

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 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 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	5	6	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	2.9 (± 5.7)	1.8 (± 6.1)	7.7 (± 9.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 34

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 34

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 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 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	5	5	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	5.6 (± 6.7)	0 (± 8.6)	6.4 (± 10.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

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 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 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	11	6	5	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	3.5 (± 7.1)	0.7 (± 7.9)	6.4 (± 10.9)	

Statistical analyses

No statistical analyses for this end point

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

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

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	11	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	1.3 (± 3.6)	0 (± 2.4)	0.7 (± 3.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 10

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 10

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 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 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	11	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	2.5 (± 3)	2.1 (± 4.7)	1.1 (± 3.4)	

Statistical analyses

No statistical analyses for this end point

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

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

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	11	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	3 (± 3.1)	2.6 (± 5.1)	2.3 (± 4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 14

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 14

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 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 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	11	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	2.8 (± 2.6)	2.7 (± 3.4)	4 (± 2)	

Statistical analyses

No statistical analyses for this end point

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

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

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	11	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	2.5 (± 2.1)	0 (± 3.9)	2.4 (± 2.1)	

Statistical analyses

No statistical analyses for this end point

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

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

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	10	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	2.8 (± 2.3)	1.6 (± 3)	3.6 (± 2.3)	

Statistical analyses

No statistical analyses for this end point

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

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

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	8	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	1.8 (± 2.7)	-0.9 (± 4.9)	2.6 (± 2.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 28

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 28

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 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 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	7	7	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	2.1 (± 2.7)	-1 (± 4.6)	2.4 (± 3.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 32

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 32

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 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 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	5	6	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	1.3 (± 3.4)	-0.6 (± 2.9)	3.3 (± 2.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 34

End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 34

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 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 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	5	5	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	3 (± 3)	0 (± 3.4)	3 (± 3.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Last Visit (Week 34 for completers or the

Withdrawal Visit for premature withdrawals)	
End point title	Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

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 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 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	10	6	5	
Units: score on a scale				
arithmetic mean (standard deviation)				
mean (standard deviation)	1.7 (± 3.4)	-1.3 (± 4.5)	3 (± 3.1)	

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 (N00291668)). '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	12	7	7	
Units: mg/L				
geometric mean (full range (min-max))				
geometric mean (full range)	19.58 (4 to 60)	14.97 (10 to 25)	26.45 (16 to 50)	

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	12	7	7	
Units: mg/L				
geometric mean (full range (min-max))				
geometric mean (full range)	22.06 (8 to 76)	11.91 (4 to 41)	16.7 (1 to 55)	

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 10

End point title	C-Reactive Protein (CRP) Level at Week 10

End point description:

End point type	Secondary

End point timeframe:

Week 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 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	12	7	7	
Units: mg/L				
geometric mean (full range (min-max))				
geometric mean (full range)	7.76 (2 to 40)	5.62 (3 to 13)	12.01 (1 to 34)	

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	12	7	7	
Units: mg/L				
geometric mean (full range (min-max))				
geometric mean (full range)	7.82 (2 to 31)	7.06 (3 to 14)	13.39 (1 to 54)	

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 14

End point title	C-Reactive Protein (CRP) Level at Week 14

End point description:

End point type	Secondary

End point timeframe:

Week 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 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	12	7	7	
Units: mg/L				
geometric mean (full range (min-max))				
geometric mean (full range)	9.57 (2 to 32)	6.32 (4 to 14)	15.3 (1 to 41)	

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	12	7	7	
Units: mg/L				
geometric mean (full range (min-max))				
geometric mean (full range)	12.54 (3 to 35)	12.23 (3 to 45)	15.1 (1 to 36)	

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	11	7	7	
Units: mg/L				
geometric mean (full range (min-max))				
geometric mean (full range)	12.27 (1 to 74)	13.24 (4 to 50)	14.99 (1 to 53)	

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	9	7	7	
Units: mg/L				
geometric mean (full range (min-max))				
geometric mean (full range)	9.11 (1 to 45)	14.16 (4 to 33)	15.7 (1 to 38)	

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 28

End point title	C-Reactive Protein (CRP) Level at Week 28

End point description:

End point type	Secondary

End point timeframe:

Week 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 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	7	7	
Units: mg/L				
geometric mean (full range (min-max))				
geometric mean (full range)	8.79 (1 to 24)	14.25 (4 to 40)	26.81 (0 to 33)	

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 32

End point title	C-Reactive Protein (CRP) Level at Week 32

End point description:

End point type	Secondary

End point timeframe:

Week 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 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	5	6	
Units: mg/L				
geometric mean (full range (min-max))				
geometric mean (full range)	15.28 (3 to 45)	10.27 (2 to 24)	16.71 (1 to 48)	

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 34

End point title	C-Reactive Protein (CRP) Level at Week 34

End point description:

End point type	Secondary

End point timeframe:

Week 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 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	5	5	
Units: mg/L				
geometric mean (full range (min-max))				
geometric mean (full range)	9.19 (1 to 40)	6.23 (2 to 16)	23.52 (0 to 81)	

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

End point title	C-Reactive Protein (CRP) Level at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

End point description:

End point type	Secondary

End point timeframe:

Last Visit (Week 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 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	11	6	5	
Units: mg/L				
geometric mean (full range (min-max))				
geometric mean (full range)	11.25 (1 to 75)	8.46 (2 to 39)	23.52 (0 to 81)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 8 divided by the CRP Level at Week 0

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	12	7	7	
Units: ratio				
geometric mean (full range (min-max))				
geometric mean (full range)	1.13 (0.4 to 4.3)	0.8 (0.2 to 4.1)	0.63 (0 to 3.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) level at Week 10 to CRP level at Week 0

End point title	Ratio of C-Reactive Protein (CRP) level at Week 10 to CRP level at Week 0

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 10 divided by the CRP Level at Week 0

End point type	Secondary

End point timeframe:

Week 0 and Week 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 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	12	7	7	
Units: ratio				
geometric mean (full range (min-max))				
geometric mean (full range)	0.4 (0.1 to 1.5)	0.38 (0.1 to 1.2)	0.45 (0 to 2)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 12 divided by the CRP Level at Week 0

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	12	7	7	
Units: ratio				
geometric mean (full range (min-max))				
geometric mean (full range)	0.4 (0.1 to 2)	0.47 (0.2 to 1.1)	0.51 (0 to 3.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) level at Week 14 to CRP level at Week 0

End point title	Ratio of C-Reactive Protein (CRP) level at Week 14 to CRP level at Week 0

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 14 divided by the CRP Level at Week 0

End point type	Secondary

End point timeframe:

Week 0 and Week 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 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	12	7	7	
Units: ratio				
geometric mean (full range (min-max))				
geometric mean (full range)	0.49 (0.1 to 5)	0.42 (0.2 to 1)	0.58 (0 to 2.4)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 16 divided by the CRP Level at Week 0

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	12	7	7	
Units: ratio				
geometric mean (full range (min-max))				
geometric mean (full range)	0.64 (0.1 to 5.3)	0.82 (0.3 to 4.1)	0.57 (0 to 2.3)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 20 divided by the CRP Level at Week 0

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	11	7	7	
Units: ratio				
geometric mean (full range (min-max))				
geometric mean (full range)	0.64 (0 to 5.5)	0.88 (0.3 to 4.5)	0.57 (0 to 3.1)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 24 divided by the CRP Level at Week 0

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	7	7	
Units: ratio				
geometric mean (full range (min-max))				
geometric mean (full range)	0.48 (0 to 3.5)	0.95 (0.4 to 2.4)	0.59 (0 to 1.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) level at Week 28 to CRP level at Week 0

End point title	Ratio of C-Reactive Protein (CRP) level at Week 28 to CRP level at Week 0

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 28 divided by the CRP Level at Week 0

End point type	Secondary

End point timeframe:

Week 0 and Week 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 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	7	7	
Units: ratio				
geometric mean (full range (min-max))				
geometric mean (full range)	0.46 (0 to 2.8)	0.95 (0.2 to 2.7)	1.06 (0 to 2.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) level at Week 32 to CRP level at Week 0

End point title	Ratio of C-Reactive Protein (CRP) level at Week 32 to CRP level at Week 0

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 32 divided by the CRP Level at Week 0

End point type	Secondary

End point timeframe:

Week 0 and Week 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 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	5	6	
Units: ratio				
geometric mean (full range (min-max))				
geometric mean (full range)	0.9 (0.1 to 4.6)	0.64 (0.2 to 1.2)	0.62 (0 to 2.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) level at Week 34 to CRP level at Week 0

End point title	Ratio of C-Reactive Protein (CRP) level at Week 34 to CRP level at Week 0

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 34 divided by the CRP Level at Week 0

End point type	Secondary

End point timeframe:

Week 0 and Week 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 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	5	5	
Units: ratio				
geometric mean (full range (min-max))				
geometric mean (full range)	0.54 (0 to 2.8)	0.39 (0.2 to 1.6)	1.07 (0 to 3.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) level at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals) to CRP level at Week 0

End point title	Ratio of C-Reactive Protein (CRP) level at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals) to CRP level at Week 0

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)divided by the CRP Level at Week 0

End point type	Secondary

End point timeframe:

Week 0 and Last Visit (Week 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 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	11	6	5	
Units: ratio				
geometric mean (full range (min-max))				
geometric mean (full range)	0.59 (0 to 2.8)	0.54 (0.2 to 2.8)	1.07 (0 to 3.5)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

70-point responders are subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0. 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	12	7	7	
Units: percentage of subjects				
number (not applicable)				
Percentage of 70-point responders	33.3	28.6	42.9	
Percentage of 70-point non-responders	66.7	71.4	57.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0 at Week 10

End point title	Percentage of subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0 at Week 10

End point description:

70-point responders are subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0. 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 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 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	12	7	7	
Units: percentage of subjects				
number (not applicable)				
Percentage of 70-point responders	66.7	85.7	100	
Percentage of 70-point non-responders	33.3	14.3	0	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

70-point responders are subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0. 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	12	7	7	
Units: percentage of subjects				
number (not applicable)				
Percentage of 70-point responders	75	71.4	85.7	
Percentage of 70-point non-responders	25	28.6	14.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0 at Week 14

End point title	Percentage of subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0 at Week 14

End point description:

70-point responders are subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of

≥70 points from Week 0. 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 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 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	12	7	7	
Units: percentage of subjects				
number (not applicable)				
Percentage of 70-point responders	100	100	100	
Percentage of 70-point non-responders	0	0	0	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

70-point responders are subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0. 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	12	7	7	
Units: percentage of subjects				
number (not applicable)				
Percentage of 70-point responders	83.3	57.1	100	
Percentage of 70-point non-responders	16.7	42.9	0	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

70-point responders are subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0. 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	12	7	7	
Units: percentage of subjects				
number (not applicable)				
Percentage of 70-point responders	75	71.4	85.7	
Percentage of 70-point non-responders	25	28.6	14.3	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

70-point responders are subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0. 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	12	7	7	
Units: percentage of subjects				
number (not applicable)				
Percentage of 70-point responders	50	71.4	100	
Percentage of 70-point non-responders	50	28.6	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0 at Week 28

End point title	Percentage of subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0 at Week 28

End point description:

70-point responders are subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0. 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 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 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	12	7	7	
Units: percentage of subjects				
number (not applicable)				
Percentage of 70-point responders	58.3	71.4	85.7	
Percentage of 70-point non-responders	41.7	28.6	14.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0 at Week 32

End point title	Percentage of subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0 at Week 32

End point description:

70-point responders are subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of

≥70 points from Week 0. 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 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 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	12	7	7	
Units: percentage of subjects				
number (not applicable)				
Percentage of 70-point responders	41.7	57.1	57.1	
Percentage of 70-point non-responders	58.3	42.9	42.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0 at Week 34

End point title	Percentage of subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0 at Week 34

End point description:

70-point responders are subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0. 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 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 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	12	7	7	
Units: percentage of subjects				
number (not applicable)				
Percentage of 70-point responders	66.7	42.9	42.9	
Percentage of 70-point non-responders	33.3	57.1	57.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0 at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

End point title	Percentage of subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0 at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

End point description:

70-point responders are subjects achieving a reduction in Crohn’s Disease Activity Index (CDAI) score of ≥70 points from Week 0. 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 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 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	12	7	7	
Units: percentage of subjects				
number (not applicable)				
Percentage of 70-point responders	66.7	42.9	42.9	
Percentage of 70-point non-responders	33.3	57.1	57.1	

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 14 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 14 to Week 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is the visit at which response to re-induction is assessed and 'Week 34' is 26 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	12	7	7	
Units: subjects				
Number of subjects	1	1	1	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse event data summarized in the first four columns 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 36 weeks).

Adverse event reporting additional description:

For the fifth column, 'Total 2', this presents the data summarized in 'Total 1' PLUS adverse event data from the double-blind main study for subjects who received certolizumab pegol (CZP) in the main study and then entered this extension study (i.e., up to 44 weeks).

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 (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

Reporting group title	CZP 400 mg / CZP 200 mg

Reporting group description:

Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 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 (2014-004399-42)

Reporting group title	CZP 400 mg / CZP 400 mg

Reporting group description:

Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 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 (2014-004399-42)

Reporting group title	Total 1 (This extension study only)

Reporting group description:

This includes all adverse event data collected in this extension study for all 46 subjects who entered this extension study.

Serious adverse events	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 18 (5.56%)	3 / 13 (23.08%)	4 / 15 (26.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	3 / 15 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			

Psychotic disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteomalacia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	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
Infections and infestations			
Perianal abscess			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (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
Pulmonary tuberculosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Electrolyte imbalance			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	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
Tetany			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	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

Serious adverse events	Total 1 (This extension study only)		
Total subjects affected by serious			

adverse events			
subjects affected / exposed	8 / 46 (17.39%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	4 / 46 (8.70%)		
occurrences causally related to treatment / all	2 / 4		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Psychotic disorder			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Suicide attempt			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Osteomalacia			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Perianal abscess			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary tuberculosis			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Electrolyte imbalance			

subjects affected / exposed	1 / 46 (2.17%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Tetany			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	CZP 400 mg / Placebo	CZP 400 mg / CZP 200 mg	CZP 400 mg / CZP 400 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 18 (83.33%)	10 / 13 (76.92%)	13 / 15 (86.67%)
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Injection site eyrthema			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	2 / 18 (11.11%)	6 / 13 (46.15%)	3 / 15 (20.00%)
occurrences (all)	2	9	3
Swelling			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Pneumothorax			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 18 (0.00%)	2 / 13 (15.38%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Depressive symptom			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Emotional distress			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Initial insomnia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Investigations			
Blood calcium decreased			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Blood potassium decreased			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
DNA antibody positive			

subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Haemoglobin decreased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
White blood cell count decreased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 18 (0.00%)	2 / 13 (15.38%)	0 / 15 (0.00%)
occurrences (all)	0	3	0
Excoriation			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Foot fracture			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Rib fracture			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Nervous system disorders			
Dizziness postural			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Headache			

subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 18 (5.56%)	2 / 13 (15.38%)	0 / 15 (0.00%)
occurrences (all)	1	2	0
Loss of consciousness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Eye disorders			
Ocular hyperaemia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Crohn's disease			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Duodenal ulcer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Gastroduodenitis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Nausea			

subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	2 / 15 (13.33%)
occurrences (all)	1	0	2
Periodontitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	2
Salivary gland disorder			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Vomiting			
subjects affected / exposed	1 / 18 (5.56%)	1 / 13 (7.69%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Dermatitis atopic			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Eczema asteatotic			

subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Muscle tightness			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
Cystitis			
subjects affected / exposed	1 / 18 (5.56%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Dental caries			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Herpes zoster			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	10 / 18 (55.56%)	5 / 13 (38.46%)	6 / 15 (40.00%)
occurrences (all)	15	8	7
Paronychia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Perianal abscess			
subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	2
Pharyngitis			
subjects affected / exposed	2 / 18 (11.11%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	2	0	1
Pulpitis dental			

subjects affected / exposed	0 / 18 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Electrolyte imbalance			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	1 / 15 (6.67%)
occurrences (all)	0	2	1
Vitamin D deficiency			
subjects affected / exposed	0 / 18 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Total 1 (This extension study only)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 46 (82.61%)		
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences (all)	1		
Injection site eyrthema			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences (all)	1		
Malaise			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	11 / 46 (23.91%)		
occurrences (all)	14		
Swelling			

subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 1		
Immune system disorders Anaphylactic reaction subjects affected / exposed occurrences (all)	 1 / 46 (2.17%) 1		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Dyspnoea subjects affected / exposed occurrences (all) Pneumothorax subjects affected / exposed occurrences (all) Rhinitis allergic subjects affected / exposed occurrences (all) Upper respiratory tract inflammation subjects affected / exposed occurrences (all)	 1 / 46 (2.17%) 1 1 / 46 (2.17%) 1 1 / 46 (2.17%) 1 2 / 46 (4.35%) 2 1 / 46 (2.17%) 1		
Psychiatric disorders Depressive symptom subjects affected / exposed occurrences (all) Emotional distress subjects affected / exposed occurrences (all) Initial insomnia subjects affected / exposed occurrences (all) Insomnia subjects affected / exposed occurrences (all)	 1 / 46 (2.17%) 1 1 / 46 (2.17%) 1 1 / 46 (2.17%) 1 1 / 46 (2.17%) 1		
Investigations			

Blood calcium decreased subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 1		
Blood potassium decreased subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 1		
DNA antibody positive subjects affected / exposed occurrences (all)	2 / 46 (4.35%) 2		
Haemoglobin decreased subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 1		
White blood cell count decreased subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 2		
Injury, poisoning and procedural complications Contusion subjects affected / exposed occurrences (all)	2 / 46 (4.35%) 3		
Excoriation subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 1		
Fall subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 1		
Foot fracture subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 1		
Rib fracture subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 1		
Cardiac disorders Palpitations subjects affected / exposed occurrences (all)	2 / 46 (4.35%) 2		
Tachycardia			

subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 1		
Nervous system disorders Dizziness postural subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all) Hypoaesthesia subjects affected / exposed occurrences (all) Loss of consciousness subjects affected / exposed occurrences (all)	 1 / 46 (2.17%) 1 1 / 46 (2.17%) 1 3 / 46 (6.52%) 3 1 / 46 (2.17%) 1		
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	 1 / 46 (2.17%) 1		
Ear and labyrinth disorders Ear discomfort subjects affected / exposed occurrences (all)	 1 / 46 (2.17%) 1		
Eye disorders Ocular hyperaemia subjects affected / exposed occurrences (all)	 1 / 46 (2.17%) 1		
Gastrointestinal disorders Abdominal pain lower subjects affected / exposed occurrences (all) Abdominal pain upper subjects affected / exposed occurrences (all) Crohn's disease subjects affected / exposed occurrences (all)	 1 / 46 (2.17%) 1 2 / 46 (4.35%) 2 1 / 46 (2.17%) 1		

Duodenal ulcer subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 1		
Gastroduodenitis subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 1		
Nausea subjects affected / exposed occurrences (all)	3 / 46 (6.52%) 3		
Periodontitis subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 2		
Salivary gland disorder subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 1		
Stomatitis subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 1		
Toothache subjects affected / exposed occurrences (all)	2 / 46 (4.35%) 2		
Vomiting subjects affected / exposed occurrences (all)	3 / 46 (6.52%) 3		
Hepatobiliary disorders Hepatic function abnormal subjects affected / exposed occurrences (all)	2 / 46 (4.35%) 2		
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 1		
Dermatitis atopic subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 1		
Dry skin			

subjects affected / exposed	1 / 46 (2.17%)		
occurrences (all)	1		
Eczema			
subjects affected / exposed	2 / 46 (4.35%)		
occurrences (all)	2		
Eczema asteatotic			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences (all)	1		
Pruritus			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Muscle tightness			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences (all)	2		
Infections and infestations			
Cystitis			
subjects affected / exposed	2 / 46 (4.35%)		
occurrences (all)	2		
Dental caries			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences (all)	1		
Herpes zoster			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences (all)	1		
Influenza			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	21 / 46 (45.65%)		
occurrences (all)	30		
Paronychia			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences (all)	1		
Perianal abscess			

subjects affected / exposed	1 / 46 (2.17%)		
occurrences (all)	2		
Pharyngitis			
subjects affected / exposed	3 / 46 (6.52%)		
occurrences (all)	3		
Pulpitis dental			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences (all)	1		
Urinary tract infection			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences (all)	1		
Electrolyte imbalance			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences (all)	1		
Hypoalbuminaemia			
subjects affected / exposed	2 / 46 (4.35%)		
occurrences (all)	3		
Vitamin D deficiency			
subjects affected / exposed	1 / 46 (2.17%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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: