Clinical trial results:
Prospective, Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial Comparing REMICADE® (infliximab) and Placebo in the Prevention of Recurrence in Crohn's Disease Patients Undergoing Surgical Resection Who Are at an Increased Risk of Recurrence

Due to the EudraCT – Results system being out of service between 31 July 2015 and 12 January 2016, these results have been published in compliance with revised timelines.

Summary

EudraCT number	2010-018431-18
Trial protocol	DE AT GB FR BE NL IT HU CZ
Global end of trial date	12 December 2014

Results information

Result version number	v1 (current)
This version publication date	14 April 2016
First version publication date	14 April 2016

Trial information

Trial identification

Sponsor protocol code	REMICADECRD3001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01190839
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	Archimedsweg 29-2333CM, Leiden, Netherlands, B235-0
Public contact	Clinical Registry Group,, Janssen Research & Development, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group,, Janssen Research & Development, ClinicalTrialsEU@its.jnj.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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 December 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 December 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to compare the efficacy of infliximab with that of placebo in the prevention of clinical recurrence of Crohn's disease (CD) prior to or at Week 76, defined as a composite endpoint that required endoscopic confirmation of recurrence, in participants who were at an increased risk of active CD recurrence following ileocolonic resection.

Protection of trial subjects:

The Safety assessment was done based on reported AEs, concomitant medication use, tuberculosis (TB) screening and evaluations throughout the study, laboratory tests (hematology, blood chemistry, antinuclear antibodies [ANA], anti-double-stranded DNA [anti-dsDNA] antibodies), and vital signs.

Background therapy: -
Evidence for comparator: -

Actual start date of recruitment	19 October 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 23
Country: Number of subjects enrolled	Austria: 11
Country: Number of subjects enrolled	Belgium: 15
Country: Number of subjects enrolled	Canada: 23
Country: Number of subjects enrolled	Czech Republic: 13
Country: Number of subjects enrolled	Germany: 26
Country: Number of subjects enrolled	France: 21
Country: Number of subjects enrolled	United Kingdom: 12
Country: Number of subjects enrolled	Hungary: 13
Country: Number of subjects enrolled	Israel: 10
Country: Number of subjects enrolled	Italy: 51
Country: Number of subjects enrolled	Netherlands: 6
Country: Number of subjects enrolled	New Zealand: 11
Country: Number of subjects enrolled	Poland: 7
Country: Number of subjects enrolled	United States: 55
Worldwide total number of subjects	297
EEA total number of subjects	175

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	286
From 65 to 84 years	11
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Approximately 290 subjects were planned to be enrolled. A total of 297 subjects were randomized (150 to the placebo group and 147 to the infliximab 5 mg/kg group). There were 291 subjects who received at least 1 administration of study agent. Of these subjects, 2 who were randomized to the placebo group received 1 infusion of infliximab 5 mg/kg.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants randomized to receive placebo at Week 0 and then every 8 weeks thereafter through Week 200.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants were administered with Placebo intravenously once every 8 weeks.

Arm title	Infliximab 5 milligram per kilogram (mg/kg)

Arm description:

Participants randomized to receive Infliximab 5 milligram per kilogram (mg/kg) at Week 0 and then every 8 weeks thereafter through Week 200.

Arm type	Experimental
Investigational medicinal product name	Infliximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants were administered with Infliximab 5 milligram (mg) intravenously once every 8 weeks.

Number of subjects in period 1	Placebo	Infliximab 5 milligram per kilogram (mg/kg)
Started	150	147
Completed	0	0
Not completed	150	147
Adverse event, serious fatal	1	-
Adverse event, non-fatal	15	23
Other	108	103
Adverse event, serious non-fatal	17	18
Lost to follow-up	7	1
Protocol deviation	2	2

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants randomized to receive placebo at Week 0 and then every 8 weeks thereafter through Week 200.	
Reporting group title	Infliximab 5 milligram per kilogram (mg/kg)
Reporting group description:	
Participants randomized to receive Infliximab 5 milligram per kilogram (mg/kg) at Week 0 and then every 8 weeks thereafter through Week 200.	

Reporting group values	Placebo	Infliximab 5 milligram per kilogram (mg/kg)	Total
Number of subjects	150	147	297
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	147	139	286
From 65 to 84 years	3	8	11
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	35.4	37.1	
standard deviation	± 12.41	± 13.49	-
Title for Gender Units: subjects			
Female	69	70	139
Male	81	77	158

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants randomized to receive placebo at Week 0 and then every 8 weeks thereafter through Week 200.	
Reporting group title	Infliximab 5 milligram per kilogram (mg/kg)
Reporting group description:	
Participants randomized to receive Infliximab 5 milligram per kilogram (mg/kg) at Week 0 and then every 8 weeks thereafter through Week 200.	

Primary: Percentage of participants With Clinical Recurrence (CR) of Crohn's Disease (CD) Prior to or at Week 76

End point title	Percentage of participants With Clinical Recurrence (CR) of Crohn's Disease (CD) Prior to or at Week 76
End point description:	
CR criteria:1) >= 70-point increase from baseline in Crohn’s Disease Activity Index (CDAI) score [CDAI score ranges from 0 to 600; higher score indicates higher disease activities];2)CDAI >=200;3)Evidence of endoscopic recurrence [ileal Rutgeerts score of >=i2 at anastomotic site or its equivalent in GI tract] and 4)A negative stool test for C. difficile toxin (the opinion of the investigator, the participant's symptoms are predominantly diarrheal); or at least 1 of followings:1) developing a new draining external fistula;2)re-opening and draining of a previously existing external fistula;3)developing new internal fistula.4)developing a new perianal abscess or 5) developing a new intra-abdominal abscess more than 3 months after date of index surgery. Participants who had a treatment failure (initiated a prohibited CD medication, had prohibited use of CD medication , or had a surgery for CD) before or at Week were considered to have had clinical recurrence prior to or at week 76.	
End point type	Primary
End point timeframe:	
Baseline up to Week 76	

End point values	Placebo	Infliximab 5 milligram per kilogram (mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	150	147		
Units: percentage of participants				
number (not applicable)	20	12.9		

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
The proportion of subjects was summarized and compared between the infliximab 5 mg/kg group and the placebo group using a 2-sided Cochran-Mantel-Haenszel chi-square test, stratified by the number of risk factors for recurrence of active CD (1 or >1) and baseline use of an immunomodulator (yes or no), at significance level of 0.05. A fixed sequence testing procedure was employed to control the overall Type I error rate at the 0.05 level over the primary and secondary endpoints.	

Comparison groups	Placebo v Infliximab 5 milligram per kilogram (mg/kg)
Number of subjects included in analysis	297
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.097
Method	Cochran-Mantel-Haenszel chi-square test

Secondary: Percentage of Participants With Endoscopic Recurrence of CD Prior to or at Week 76

End point title	Percentage of Participants With Endoscopic Recurrence of CD Prior to or at Week 76

End point description:

Endoscopic recurrence is defined as an ileal Rutgeert's score of >= i2 either at the anastomotic site or elsewhere in the gastrointestinal tract. In addition, participants who had a treatment failure (initiated a prohibited CD medication, had a prohibited use of a CD medication, or had a surgery for CD) prior to Week 76, or who developed a new draining external fistula or re-opening and draining of a previously existing external fistula or developed a new internal fistula, new perianal abscess or new intra-abdominal abscess more than 3 months after the date of the index surgery were considered to have had endoscopic recurrence prior to or at Week 76.

End point type	Secondary

End point timeframe:

Baseline up to Week 76

End point values	Placebo	Infliximab 5 milligram per kilogram (mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	150	147		
Units: Percentage of participants				
number (not applicable)	60	30.6		

Statistical analyses

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

The proportion of participants was summarized and compared between the infliximab 5 mg/kg group and the placebo group using a 2-sided Cochran-Mantel-Haenszel chi-square test, stratified by the number of risk factors for recurrence of active CD (1 or >1) and baseline use of an immunomodulator (yes or no), at significance level of 0.05.

Comparison groups	Placebo v Infliximab 5 milligram per kilogram (mg/kg)
Number of subjects included in analysis	297
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Secondary: Percentage of Participants With Clinical Recurrence (CR) of Crohn's Disease (CD) Prior to or at Week 104

End point title	Percentage of Participants With Clinical Recurrence (CR) of Crohn's Disease (CD) Prior to or at Week 104

End point description:

CR criteria:1) >= 70-point increase from baseline in Crohn’s Disease Activity Index (CDAI) score [CDAI score ranges from 0 to 600; higher score indicates higher disease activities];2)CDAI score >=200;3)Evidence of endoscopic recurrence [ileal Rutgeerts score of >=i2 at anastomotic site or its equivalent in GI tract] and 4)A negative stool test for C. difficile toxin (the opinion of the investigator, the participant's symptoms are predominantly diarrheal); or at least 1 of followings:1) developing a new draining external fistula;2)re-opening and draining of a previously existing external fistula;3)developing a new internal fistula.4)developing a new perianal abscess or 5) developing a new intra-abdominal abscess more than 3 months after date of index surgery. In addition, participants who had a treatment failure (a prohibited CD medication, had prohibited use of CD medication , or had a surgery for CD) were considered to have had clinical recurrence prior to or at week 104.

End point type	Secondary

End point timeframe:

Baseline up to Week 104

End point values	Placebo	Infliximab 5 milligram per kilogram (mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	150	147		
Units: Percentage of participants				
number (not applicable)	25.3	17.7		

Statistical analyses

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

The proportion of participants was summarized and compared between the infliximab 5 mg/kg group and the placebo group using a 2-sided Cochran-Mantel-Haenszel chi-square test, stratified by the number of risk factors for recurrence of active CD (1 or >1) and baseline use of an immunomodulator (yes or no), at significance level of 0.05.

Comparison groups	Placebo v Infliximab 5 milligram per kilogram (mg/kg)
Number of subjects included in analysis	297
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.098
Method	Cochran-Mantel-Haenszel chi-square test

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline to the final visit (8 weeks after a Participants final infusion of study agent)

Adverse event reporting additional description:

All participants who received at least 1 infusion of study drug. Placebo, Infliximab 5mg/kg includes data up to dose increase. First Placebo Then Infliximab 5 mg/kg, First Infliximab 5 mg/kg Then Infliximab 10 mg/kg includes data from time of dose increase through the final visit.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	Placebo

Reporting group description:

Subjects treated with placebo through the final visit or through a protocol defined dose increase. If a subject had a protocol defined dose increase prior to or at the final visit, only safety results prior to the dose increase will be included in this group.

Reporting group title	Infliximab 5 mg/kg

Reporting group description:

Subjects treated with Infliximab 5 mg/kg at any time through the final visit or through a protocol defined dose increase. If a subject had a protocol defined dose increase prior to or at the final visit, only safety results prior to the dose increase will be included in this group.

Reporting group title	First Placebo Then Infliximab 5 mg/kg

Reporting group description:

Subjects had a protocol defined dose increase from Placebo to infliximab 5 mg/kg prior to or at the final visit. Only safety results after start of infliximab were included in this group.

Reporting group title	First Infliximab 5 mg/kg Then Infliximab 10 mg/kg

Reporting group description:

Subjects had a protocol defined dose increase from infliximab 5 mg/kg to infliximab 10 mg/kg prior to or at the final visit. Only safety results after the dose increase were included in this group.

Serious adverse events	Placebo	Infliximab 5 mg/kg	First Placebo Then Infliximab 5 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	36 / 146 (24.66%)	32 / 145 (22.07%)	5 / 27 (18.52%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Cancer			

subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid Cancer			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (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
Surgical and medical procedures			
Intestinal Resection			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (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
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal Death			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Malaise			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Drug Hypersensitivity			

subjects affected / exposed	1 / 146 (0.68%)	1 / 145 (0.69%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serum Sickness			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Reproductive system and breast disorders			
Colpocele			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pleurisy			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Injury, poisoning and procedural complications			
Anastomotic Leak			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic Stenosis			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Incisional Hernia			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion Related Reaction			

subjects affected / exposed	0 / 146 (0.00%)	3 / 145 (2.07%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Diarrhoea			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pain			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib Fracture			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Road Traffic Accident			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Scar			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon Rupture			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Acute Coronary Syndrome			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Acute Myocardial Infarction			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Arteriosclerosis Coronary Artery			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Atrial Flutter			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Coronary Artery Disease			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Radiculitis			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 146 (2.05%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal disorders			
Abdominal Adhesions			
subjects affected / exposed	2 / 146 (1.37%)	1 / 145 (0.69%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Hernia			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Abdominal Pain			
subjects affected / exposed	4 / 146 (2.74%)	1 / 145 (0.69%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Upper			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Fistula			
subjects affected / exposed	2 / 146 (1.37%)	0 / 145 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's Disease			
subjects affected / exposed	5 / 146 (3.42%)	1 / 145 (0.69%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal Stenosis			

subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Ileus			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Intestinal Obstruction			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Perforation			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	2 / 146 (1.37%)	3 / 145 (2.07%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile Duct Stone			

subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Biliary Colic			
subjects affected / exposed	1 / 146 (0.68%)	1 / 145 (0.69%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus Ureteric			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Urinary			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Renal Colic			
subjects affected / exposed	0 / 146 (0.00%)	2 / 145 (1.38%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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

Fistula			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lupus-Like Syndrome			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Spinal Column Stenosis			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal Abscess			
subjects affected / exposed	2 / 146 (1.37%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Wall Abscess			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Anal Abscess			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus Infection			

subjects affected / exposed	2 / 146 (1.37%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal Cyst			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Pneumonia Legionella			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Postoperative Wound Infection			
subjects affected / exposed	1 / 146 (0.68%)	1 / 145 (0.69%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			

subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Sepsis			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma Site Infection			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Tuberculosis			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Urinary Tract Infection			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Infection			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (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
Hyperglycaemia			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tetany			

subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	First Infliximab 5 mg/kg Then Infliximab 10 mg/kg		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 9 (22.22%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal Cancer			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thyroid Cancer			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Intestinal Resection			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal Death			

subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Malaise			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Drug Hypersensitivity			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Serum Sickness			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Colpocele			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pleurisy			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Anastomotic Leak			

subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anastomotic Stenosis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Incisional Hernia				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infusion Related Reaction				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post Procedural Diarrhoea				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Procedural Pain				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rib Fracture				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Road Traffic Accident				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Scar				

subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tendon Rupture				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Hydrocele				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Acute Coronary Syndrome				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute Myocardial Infarction				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arteriosclerosis Coronary Artery				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial Flutter				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary Artery Disease				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Nervous system disorders			
Radiculitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancytopenia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal Adhesions			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal Hernia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal Pain			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Abdominal Pain Upper			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal Fistula			

subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Crohn's Disease				
subjects affected / exposed	2 / 9 (22.22%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enteritis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ileal Stenosis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal Hernia				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal Obstruction				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal Perforation				

subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower Gastrointestinal Haemorrhage				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small Intestinal Obstruction				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Umbilical Hernia				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Bile Duct Stone				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Biliary Colic				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Pruritus				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				

Calculus Ureteric				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Calculus Urinary				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal Colic				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Arthralgia				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fistula				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lupus-Like Syndrome				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Spinal Column Stenosis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Abdominal Abscess				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal Wall Abscess				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anal Abscess				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cytomegalovirus Infection				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erysipelas				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis Viral				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pilonidal Cyst				

subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia Legionella				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Postoperative Wound Infection				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal Sepsis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stoma Site Infection				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tuberculosis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary Tract Infection				

subjects affected / exposed	1 / 9 (11.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Viral Infection			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperglycaemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tetany			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Placebo	Infliximab 5 mg/kg	First Placebo Then Infliximab 5 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	122 / 146 (83.56%)	121 / 145 (83.45%)	18 / 27 (66.67%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Dysplastic Naevus			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Squamous Cell Carcinoma of Skin			
subjects affected / exposed	0 / 146 (0.00%)	2 / 145 (1.38%)	0 / 27 (0.00%)
occurrences (all)	0	17	0
Vascular disorders			

Flushing			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	3 / 146 (2.05%)	8 / 145 (5.52%)	1 / 27 (3.70%)
occurrences (all)	3	8	1
Poor Venous Access			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Pregnancy			
subjects affected / exposed	3 / 146 (2.05%)	2 / 145 (1.38%)	0 / 27 (0.00%)
occurrences (all)	3	2	0
General disorders and administration site conditions			
Adverse Drug Reaction			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
Asthenia			
subjects affected / exposed	8 / 146 (5.48%)	5 / 145 (3.45%)	1 / 27 (3.70%)
occurrences (all)	12	6	2
Fatigue			
subjects affected / exposed	10 / 146 (6.85%)	8 / 145 (5.52%)	1 / 27 (3.70%)
occurrences (all)	11	8	1
Infusion Site Extravasation			
subjects affected / exposed	1 / 146 (0.68%)	1 / 145 (0.69%)	0 / 27 (0.00%)
occurrences (all)	1	1	0
Local Swelling			
subjects affected / exposed	1 / 146 (0.68%)	2 / 145 (1.38%)	0 / 27 (0.00%)
occurrences (all)	1	2	0
Pyrexia			
subjects affected / exposed	17 / 146 (11.64%)	22 / 145 (15.17%)	1 / 27 (3.70%)
occurrences (all)	23	25	1
Immune system disorders			
Drug Hypersensitivity			
subjects affected / exposed	1 / 146 (0.68%)	1 / 145 (0.69%)	2 / 27 (7.41%)
occurrences (all)	1	1	2

Social circumstances			
Pregnancy of Partner			
subjects affected / exposed	2 / 146 (1.37%)	2 / 145 (1.38%)	2 / 27 (7.41%)
occurrences (all)	2	2	2
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Bronchiectasis			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	17 / 146 (11.64%)	14 / 145 (9.66%)	0 / 27 (0.00%)
occurrences (all)	19	17	0
Oropharyngeal Pain			
subjects affected / exposed	10 / 146 (6.85%)	14 / 145 (9.66%)	0 / 27 (0.00%)
occurrences (all)	21	16	0
Pleural Effusion			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Respiratory Distress			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Depression			
subjects affected / exposed	4 / 146 (2.74%)	9 / 145 (6.21%)	0 / 27 (0.00%)
occurrences (all)	5	9	0
Insomnia			
subjects affected / exposed	1 / 146 (0.68%)	7 / 145 (4.83%)	1 / 27 (3.70%)
occurrences (all)	1	10	1
Investigations			
Blood Calcium Decreased			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Blood Iron Decreased			

subjects affected / exposed	1 / 146 (0.68%)	2 / 145 (1.38%)	0 / 27 (0.00%)
occurrences (all)	1	2	0
Body Temperature Increased			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	2 / 27 (7.41%)
occurrences (all)	0	1	2
Faecal Calprotectin			
subjects affected / exposed	0 / 146 (0.00%)	3 / 145 (2.07%)	0 / 27 (0.00%)
occurrences (all)	0	3	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	3 / 146 (2.05%)	2 / 145 (1.38%)	0 / 27 (0.00%)
occurrences (all)	4	2	0
Facial Bones Fracture			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Infusion Related Reaction			
subjects affected / exposed	3 / 146 (2.05%)	7 / 145 (4.83%)	2 / 27 (7.41%)
occurrences (all)	3	12	3
Joint Injury			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
Lower Limb Fracture			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
Post Procedural Diarrhoea			
subjects affected / exposed	0 / 146 (0.00%)	2 / 145 (1.38%)	0 / 27 (0.00%)
occurrences (all)	0	4	0
Pulmonary Contusion			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness Postural			
subjects affected / exposed	2 / 146 (1.37%)	2 / 145 (1.38%)	0 / 27 (0.00%)
occurrences (all)	2	2	0
Headache			

subjects affected / exposed	31 / 146 (21.23%)	29 / 145 (20.00%)	1 / 27 (3.70%)
occurrences (all)	164	147	1
Hypoaesthesia			
subjects affected / exposed	2 / 146 (1.37%)	3 / 145 (2.07%)	1 / 27 (3.70%)
occurrences (all)	2	3	1
Hypotonia			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	2 / 146 (1.37%)	2 / 145 (1.38%)	0 / 27 (0.00%)
occurrences (all)	2	2	0
Migraine			
subjects affected / exposed	3 / 146 (2.05%)	6 / 145 (4.14%)	0 / 27 (0.00%)
occurrences (all)	31	36	0
Restless Legs Syndrome			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
Syncope			
subjects affected / exposed	2 / 146 (1.37%)	2 / 145 (1.38%)	0 / 27 (0.00%)
occurrences (all)	2	2	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	10 / 146 (6.85%)	8 / 145 (5.52%)	0 / 27 (0.00%)
occurrences (all)	11	8	0
Ear and labyrinth disorders			
Ear Pain			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Distension			
subjects affected / exposed	8 / 146 (5.48%)	8 / 145 (5.52%)	1 / 27 (3.70%)
occurrences (all)	14	10	1
Abdominal Pain			
subjects affected / exposed	36 / 146 (24.66%)	25 / 145 (17.24%)	4 / 27 (14.81%)
occurrences (all)	70	36	5
Abdominal Pain Upper			

subjects affected / exposed	8 / 146 (5.48%)	8 / 145 (5.52%)	0 / 27 (0.00%)
occurrences (all)	16	12	0
Abdominal Symptom			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Anal Fistula			
subjects affected / exposed	2 / 146 (1.37%)	1 / 145 (0.69%)	2 / 27 (7.41%)
occurrences (all)	2	1	3
Aphthous Stomatitis			
subjects affected / exposed	2 / 146 (1.37%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	2	0	0
Crohn's Disease			
subjects affected / exposed	13 / 146 (8.90%)	10 / 145 (6.90%)	6 / 27 (22.22%)
occurrences (all)	14	10	8
Diarrhoea			
subjects affected / exposed	27 / 146 (18.49%)	24 / 145 (16.55%)	2 / 27 (7.41%)
occurrences (all)	117	32	2
Diarrhoea Haemorrhagic			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	5 / 146 (3.42%)	10 / 145 (6.90%)	1 / 27 (3.70%)
occurrences (all)	7	10	1
Frequent Bowel Movements			
subjects affected / exposed	7 / 146 (4.79%)	2 / 145 (1.38%)	0 / 27 (0.00%)
occurrences (all)	7	2	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	5 / 146 (3.42%)	5 / 145 (3.45%)	1 / 27 (3.70%)
occurrences (all)	9	12	1
Haemorrhoids			
subjects affected / exposed	7 / 146 (4.79%)	1 / 145 (0.69%)	1 / 27 (3.70%)
occurrences (all)	9	1	1
Ileal Ulcer			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Mouth Ulceration			

subjects affected / exposed	1 / 146 (0.68%)	4 / 145 (2.76%)	0 / 27 (0.00%)
occurrences (all)	1	4	0
Nausea			
subjects affected / exposed	16 / 146 (10.96%)	25 / 145 (17.24%)	0 / 27 (0.00%)
occurrences (all)	24	58	0
Rectal Haemorrhage			
subjects affected / exposed	1 / 146 (0.68%)	6 / 145 (4.14%)	1 / 27 (3.70%)
occurrences (all)	1	7	2
Toothache			
subjects affected / exposed	5 / 146 (3.42%)	5 / 145 (3.45%)	1 / 27 (3.70%)
occurrences (all)	8	7	1
Vomiting			
subjects affected / exposed	11 / 146 (7.53%)	14 / 145 (9.66%)	0 / 27 (0.00%)
occurrences (all)	21	18	0
Skin and subcutaneous tissue disorders			
Dermal Cyst			
subjects affected / exposed	0 / 146 (0.00%)	1 / 145 (0.69%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
Hidradenitis			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	5 / 146 (3.42%)	10 / 145 (6.90%)	2 / 27 (7.41%)
occurrences (all)	6	11	2
Rash			
subjects affected / exposed	9 / 146 (6.16%)	8 / 145 (5.52%)	0 / 27 (0.00%)
occurrences (all)	16	11	0
Skin Fissures			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 146 (0.68%)	4 / 145 (2.76%)	1 / 27 (3.70%)
occurrences (all)	13	6	1
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	32 / 146 (21.92%)	26 / 145 (17.93%)	4 / 27 (14.81%)
occurrences (all)	60	36	7
Back Pain			
subjects affected / exposed	9 / 146 (6.16%)	16 / 145 (11.03%)	1 / 27 (3.70%)
occurrences (all)	11	19	1
Musculoskeletal Pain			
subjects affected / exposed	3 / 146 (2.05%)	4 / 145 (2.76%)	0 / 27 (0.00%)
occurrences (all)	3	4	0
Myalgia			
subjects affected / exposed	3 / 146 (2.05%)	8 / 145 (5.52%)	0 / 27 (0.00%)
occurrences (all)	3	8	0
Osteoporosis			
subjects affected / exposed	1 / 146 (0.68%)	0 / 145 (0.00%)	1 / 27 (3.70%)
occurrences (all)	1	0	1
Infections and infestations			
Anal Abscess			
subjects affected / exposed	4 / 146 (2.74%)	0 / 145 (0.00%)	2 / 27 (7.41%)
occurrences (all)	4	0	2
Bronchitis			
subjects affected / exposed	10 / 146 (6.85%)	7 / 145 (4.83%)	1 / 27 (3.70%)
occurrences (all)	15	8	2
Conjunctivitis			
subjects affected / exposed	2 / 146 (1.37%)	3 / 145 (2.07%)	0 / 27 (0.00%)
occurrences (all)	3	4	0
Gastroenteritis			
subjects affected / exposed	8 / 146 (5.48%)	5 / 145 (3.45%)	0 / 27 (0.00%)
occurrences (all)	15	6	0
Gastroenteritis Salmonella			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Herpes Zoster			
subjects affected / exposed	2 / 146 (1.37%)	5 / 145 (3.45%)	1 / 27 (3.70%)
occurrences (all)	2	5	1
Infected Dermal Cyst			

subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	15 / 146 (10.27%)	12 / 145 (8.28%)	0 / 27 (0.00%)
occurrences (all)	26	16	0
Nasopharyngitis			
subjects affected / exposed	37 / 146 (25.34%)	37 / 145 (25.52%)	3 / 27 (11.11%)
occurrences (all)	86	71	3
Purulent Discharge			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	7 / 146 (4.79%)	9 / 145 (6.21%)	0 / 27 (0.00%)
occurrences (all)	8	10	0
Tooth Abscess			
subjects affected / exposed	2 / 146 (1.37%)	2 / 145 (1.38%)	0 / 27 (0.00%)
occurrences (all)	2	5	0
Upper Respiratory Tract Infection			
subjects affected / exposed	21 / 146 (14.38%)	21 / 145 (14.48%)	5 / 27 (18.52%)
occurrences (all)	35	31	5
Urinary Tract Infection			
subjects affected / exposed	7 / 146 (4.79%)	4 / 145 (2.76%)	0 / 27 (0.00%)
occurrences (all)	7	5	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 146 (0.00%)	0 / 145 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	4 / 146 (2.74%)	1 / 145 (0.69%)	0 / 27 (0.00%)
occurrences (all)	4	1	0

Non-serious adverse events	First Infliximab 5 mg/kg Then Infliximab 10 mg/kg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 9 (88.89%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Dysplastic Naevus subjects affected / exposed occurrences (all) Squamous Cell Carcinoma of Skin subjects affected / exposed occurrences (all)	 1 / 9 (11.11%) 2 1 / 9 (11.11%) 2		
Vascular disorders Flushing subjects affected / exposed occurrences (all) Hypertension subjects affected / exposed occurrences (all) Poor Venous Access subjects affected / exposed occurrences (all)	 1 / 9 (11.11%) 1 0 / 9 (0.00%) 0 1 / 9 (11.11%) 1		
Pregnancy, puerperium and perinatal conditions Pregnancy subjects affected / exposed occurrences (all)	 1 / 9 (11.11%) 1		
General disorders and administration site conditions Adverse Drug Reaction subjects affected / exposed occurrences (all) Asthenia subjects affected / exposed occurrences (all) Fatigue subjects affected / exposed occurrences (all) Infusion Site Extravasation subjects affected / exposed occurrences (all) Local Swelling subjects affected / exposed occurrences (all)	 1 / 9 (11.11%) 1 1 / 9 (11.11%) 1 0 / 9 (0.00%) 0 1 / 9 (11.11%) 1 1 / 9 (11.11%) 1		

Pyrexia subjects affected / exposed occurrences (all)	3 / 9 (33.33%) 3		
Immune system disorders Drug Hypersensitivity subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0		
Social circumstances Pregnancy of Partner subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Atelectasis subjects affected / exposed occurrences (all) Bronchiectasis subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all) Oropharyngeal Pain subjects affected / exposed occurrences (all) Pleural Effusion subjects affected / exposed occurrences (all) Respiratory Distress subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1 1 / 9 (11.11%) 1 0 / 9 (0.00%) 0 0 / 9 (0.00%) 0 1 / 9 (11.11%) 1 1 / 9 (11.11%) 1		
Psychiatric disorders Depression subjects affected / exposed occurrences (all) Insomnia	0 / 9 (0.00%) 0		

subjects affected / exposed	2 / 9 (22.22%)		
occurrences (all)	3		
Investigations			
Blood Calcium Decreased			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Blood Iron Decreased			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Body Temperature Increased			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Faecal Calprotectin			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Facial Bones Fracture			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Infusion Related Reaction			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Joint Injury			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Lower Limb Fracture			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Post Procedural Diarrhoea			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Pulmonary Contusion			

subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Nervous system disorders			
Dizziness Postural			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Headache			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Hypoaesthesia			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Hypotonia			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Lethargy			
subjects affected / exposed	2 / 9 (22.22%)		
occurrences (all)	2		
Migraine			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Restless Legs Syndrome			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Syncope			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear Pain			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Gastrointestinal disorders			

Abdominal Distension				
subjects affected / exposed	2 / 9 (22.22%)			
occurrences (all)	3			
Abdominal Pain				
subjects affected / exposed	2 / 9 (22.22%)			
occurrences (all)	3			
Abdominal Pain Upper				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences (all)	1			
Abdominal Symptom				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences (all)	1			
Anal Fistula				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences (all)	1			
Aphthous Stomatitis				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences (all)	1			
Crohn's Disease				
subjects affected / exposed	3 / 9 (33.33%)			
occurrences (all)	3			
Diarrhoea				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences (all)	1			
Diarrhoea Haemorrhagic				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences (all)	1			
Dyspepsia				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences (all)	0			
Frequent Bowel Movements				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences (all)	1			
Gastrooesophageal Reflux Disease				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences (all)	1			

Haemorrhoids				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences (all)	1			
Ileal Ulcer				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences (all)	1			
Mouth Ulceration				
subjects affected / exposed	2 / 9 (22.22%)			
occurrences (all)	2			
Nausea				
subjects affected / exposed	2 / 9 (22.22%)			
occurrences (all)	6			
Rectal Haemorrhage				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences (all)	1			
Toothache				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences (all)	1			
Vomiting				
subjects affected / exposed	2 / 9 (22.22%)			
occurrences (all)	3			
Skin and subcutaneous tissue disorders				
Dermal Cyst				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences (all)	1			
Hidradenitis				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences (all)	1			
Pruritus				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences (all)	3			
Rash				
subjects affected / exposed	2 / 9 (22.22%)			
occurrences (all)	2			
Skin Fissures				

subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Urticaria			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	2		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 9 (33.33%)		
occurrences (all)	4		
Back Pain			
subjects affected / exposed	3 / 9 (33.33%)		
occurrences (all)	5		
Musculoskeletal Pain			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Myalgia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Osteoporosis			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Infections and infestations			
Anal Abscess			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Gastroenteritis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Gastroenteritis Salmonella			

subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Herpes Zoster			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Infected Dermal Cyst			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	2		
Influenza			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	2		
Purulent Discharge			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Sinusitis			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Tooth Abscess			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Upper Respiratory Tract Infection			
subjects affected / exposed	3 / 9 (33.33%)		
occurrences (all)	5		
Urinary Tract Infection			
subjects affected / exposed	2 / 9 (22.22%)		
occurrences (all)	4		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	5		
Hypokalaemia			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	6		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 July 2010	The overall reason for the amendment was to ensure that all participants received active medication when a clinical recurrence occurred,the instructions were expanded including dosing time intervals,collection of additional follow-up information was added every 6 months for Participants who withdrew,the inclusion criterion for negative QuantiFERON-TB Gold test results prior to study agent administration was changed from 1 to 6 weeks and Rules for determining endoscopic recurrence (major secondary endpoint) based on Crohn's Disease Activity Index (CDAI) criteria for clinical recurrence in Participants who did not discontinue study agent prior to Week 76 and who did not undergo a video ileocolonoscopy or did not have an evaluable video ileocolonoscopy by Week 76 were revised.
23 November 2010	The overall reason for the amendment was to add an interim futility analysis after the first 145 randomized participants either completed 76 weeks of the study orprior to Week 76 to allow the study to be stopped early.The clinical recurrence composite primary endpoint was updated to include a negative stool test for C. difficile prior to endoscopy,added development of a new draining fistula and surgery for Crohn's disease (CD) to the definition of clinical recurrence,handling of missing data at Week 76 were revised,Specified CDAI collected during the screening period and recommendation added for starting administration of study agent within 3 hours after reconstitution and dilution.
16 March 2011	The overall reason for the amendment was to include participants who had an intra-abdominal operation for CD with an end ileostomy who were undergoing a reversal of the ileostomy within 1 year of the date of the original operation,Participants who tested positive only for HBV surface antibody were eligible for study,Preparation, handling, and storage of infliximab were updated,Time and Events Schedule updated to specify that stool studies at screening must have included a stool culture and C. difficile toxin assay,Clarification added that if a draining fistula was present within 3 months of screening, unless the fistula was removed at the index surgery and number of
28 July 2011	The overall reason for the amendment was to include the definition of clinical recurrence was modified to also include re-opening and draining of previously existing fistula, development of a new internal fistula, a new perianal abscess,under ordinary conditions through Week 208, lower endoscopic procedures were to be performed only unless medically necessary,Inclusion criterion for prior infliximab treatment was modified,those participants who had an end ileostomy who were undergoing a reversal of the ileostomy within 1 year of the date of the original operation were eligible for inclusion in the study,Description of endoscopic response evaluation was expanded,Clarified results of the video ileocolonoscopies were to be used for the analyses of endoscopic recurrence and the standard weight table was revised to include a

25 April 2013	The overall reason for the amendment was to include clarifications made to the timing of video ileocolonoscopy and the importance of verifying negative C. difficile test,interim analysis was removed,annual chest radiograph (for Tuberculosis) for participants was added,clarified that the hematocrit value from the central laboratory would be used in the calculation of the CDAI,Use of concomitant medications was revised, Video ileocolonoscopy procedures clarified,Corrected change in Inflammatory Bowel Disease Questionnaire (IBDQ) dimensions and total scores to begin at Week 8 not at baseline,Criteria for discontinuation of study agent revised to specify use of New York Heart Association classification scale for congestive heart failure,all video ileocolonoscopies performed per protocol were to be video recorded in the electronic case report form (eCRF),additional information added for reports of malignancy and premalignant conditions and Recommendation added for periodic skin examination for all participants, particularly those with risk factors for skin cancer.
17 December 2013	The overall reason for the amendment was to include revised pursuant to a Health Authority request to specify that results from the central reader were used for the primary analysis; note that the local reader result continued to be used as a component of the dose escalation process.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
12 December 2014	The study was discontinued by the sponsor following the Week 104 database lock because the primary endpoint at Week 76 and the subsequent criteria established for Week 104 were not met.	-

Notes:

Limitations and caveats

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

Limitation of the study was that participants were a lower-risk population than intended in a clinical recurrence rate and the use of the largely symptom-based CDAI score as part of the primary endpoint for clinical recurrence.

Notes: