Clinical trial results:
A randomized, double-blind, double-dummy, active controlled study of ACZ885 (canakinumab) on the treatment and prevention of gout flares in patients with frequent flares, for whom NSAIDs and/or colchicine are contraindicated, not tolerated or ineffective

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd.com/CtrdWeb/home.novfor complete trial results

Summary

EudraCT number	2010-024172-26
Trial protocol	PL
Global end of trial date	19 May 2015

Results information

Result version number	v1 (current)
This version publication date	07 July 2018
First version publication date	07 July 2018

Trial information

Trial identification

Sponsor protocol code	CACZ885H2358

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01362608
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, +41 613241111,
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, +41 613241111,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	19 May 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	19 May 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1) To confirm that canakinumab 150 mg s.c. is superior to triamcinolone acetonide 40 mg i.m. with respect to patient’s assessment of gout pain intensity in the most affected joint at 72 hours postdose (on a 0-100mm visual analog scale [VAS])

2) To confirm that canakinumab 150 mg s.c. is superior to triamcinolone acetonide 40 mg i.m. with respect to the time to the first new gout flare in observation period of 12 weeks

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 July 2011
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	Argentina: 4
Country: Number of subjects enrolled	China: 114
Country: Number of subjects enrolled	Poland: 10
Country: Number of subjects enrolled	Singapore: 8
Worldwide total number of subjects	136
EEA total number of subjects	10

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)	124
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 136 patients were randomized to treatment, 67 to canakinumab 150 mg s.c. and 69 to triamcinolone acetonide 40 mg i.m.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	ACZ885 150 mg

Arm description:

Patients were treated with canakinumab 150 mg s.c and matching placebo for triamcinolone acetonide i.m.

Arm type	Experimental
Investigational medicinal product name	canakinumab
Investigational medicinal product code	ACZ885
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

150 mg S C

Arm title	Triamcinolone acetonide 40 mg

Arm description:

triamcinolone acetonide 40 mg i.m. and matching placebo for canakinumab s.c.

Arm type	Active comparator
Investigational medicinal product name	Triamcinolone acetonide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

40 mg SC

Number of subjects in period 1	ACZ885 150 mg	Triamcinolone acetonide 40 mg
Started	67	69
Completed	63	61
Not completed	4	8
Consent withdrawn by subject	1	2
Adverse event, non-fatal	-	2
Lost to follow-up	3	1
Protocol deviation	-	1
Lack of efficacy	-	2

Baseline characteristics

Reporting groups	
Reporting group title	ACZ885 150 mg
Reporting group description:	
Patients were treated with canakinumab 150 mg s.c and matching placebo for triamcinolone acetonide i.m.	
Reporting group title	Triamcinolone acetonide 40 mg
Reporting group description:	
triamcinolone acetonide 40 mg i.m. and matching placebo for canakinumab s.c.	

Reporting group values	ACZ885 150 mg	Triamcinolone acetonide 40 mg	Total
Number of subjects	67	69	136
Age Categorical Units: participants			
Between 18 and 65 years	58	66	124
>=65 years	9	3	12
Age Continuous Units: years			
arithmetic mean	50.2	49.2	
standard deviation	± 11.98	± 11.37	-
Gender, Male/Female Units: Participants			
Female	1	2	3
Male	66	67	133

End points

End points reporting groups	
Reporting group title	ACZ885 150 mg
Reporting group description:	
Patients were treated with canakinumab 150 mg s.c and matching placebo for triamcinolone acetonide i.m.	
Reporting group title	Triamcinolone acetonide 40 mg
Reporting group description:	
triamcinolone acetonide 40 mg i.m. and matching placebo for canakinumab s.c.	

Primary: The change in the gout pain intensity in the target joint following ACZ885 administration measured by Visual Analog Scale (VAS)	
End point title	The change in the gout pain intensity in the target joint following ACZ885 administration measured by Visual Analog Scale (VAS)
End point description:	
A higher score indicates greater pain intensity. Based on the distribution of pain VAS scores in postsurgical patients (knee replacement, hysterectomy, or laparoscopic myomectomy) who described their postoperative pain intensity as none, mild, moderate, or severe, the following cut points on the pain VAS have been recommended: no pain (0 – 4 mm), mild pain (5– 44 mm), moderate pain (45–74 mm), and severe pain (75– 100 mm)	
End point type	Primary
End point timeframe:	
at 72 hours post-dose	

End point values	ACZ885 150 mg	Triamcinolone acetonide 40 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	69		
Units: units on a line				
least squares mean (standard error)	18.2 (± 3.03)	37.9 (± 3.03)		

Statistical analyses

Statistical analysis title	ACZ885 vs Triamcinolone ANCOVA
Comparison groups	ACZ885 150 mg v Triamcinolone acetonide 40 mg
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-19.69

Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.2
upper limit	-11.2

Primary: Time to first new flare: Survival analysis by treatment: Kaplan Meier Analysis

End point title	Time to first new flare: Survival analysis by treatment: Kaplan Meier Analysis

End point description:

Measure canakinumab 150 mg s.c. is superior to triamcinolone acetonide 40 mg i.m. with respect to the time to the first new gout flare in observation period of 12 weeks

End point type	Primary

End point timeframe:

12 weeks

End point values	ACZ885 150 mg	Triamcinolone acetonide 40 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	69		
Units: Participants				
number (confidence interval 95%)	5 (1.19 to 13.93)	17 (15.29 to 36.71)		

Statistical analyses

Statistical analysis title	ACZ885 vs Triamcinolone COX Regression
Comparison groups	ACZ885 150 mg v Triamcinolone acetonide 40 mg
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0043
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	0.71

Secondary: The percentage of patients with at least 1 new gout flare

End point title	The percentage of patients with at least 1 new gout flare

End point description:

End point type	Secondary

End point timeframe:

12 weeks

End point values	ACZ885 150 mg	Triamcinolone acetonide 40 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	69		
Units: participants				
1 new flare	3	15		
2 new flares	0	1		
3 new flares	0	0		
> 3 new flares	2	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Patients Assessment of Gout Pain intensity in the most effected joint (0–100mm VAS): Summary statistics by timepoint and treatment

End point title	Patients Assessment of Gout Pain intensity in the most effected joint (0–100mm VAS): Summary statistics by timepoint and treatment

End point description:

A higher score indicates greater pain intensity. Based on the distribution of pain VAS scores in postsurgical patients (knee replacement, hysterectomy, or laparoscopic myomectomy) who described their postoperative pain intensity as none, mild, moderate, or severe, the following cut points on the pain VAS have been recommended: no pain (0 – 4 mm), mild pain (5– 44 mm), moderate pain (45–74 mm), and severe pain (75– 100 mm)

End point type	Secondary

End point timeframe:

baseline through 12 weeks

End point values	ACZ885 150 mg	Triamcinolone acetonide 40 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	69		
Units: unit on a scale				
arithmetic mean (standard deviation)				
baseline	72.3 (± 13.18)	74.5 (± 12.88)		

6 hours post-dose	53 (± 22.06)	58.8 (± 23.83)		
12 hours post-dose	41.7 (± 19.56)	51.8 (± 27.07)		
24 hours post-dose	30.9 (± 18.23)	48.6 (± 29.13)		
48 hours post-dose	22 (± 18.64)	43.9 (± 30.69)		
72 hours post-dose	17.4 (± 17.02)	36.6 (± 30.62)		
7 days post-dose	10.1 (± 15.61)	24 (± 27.31)		
4 weeks post-dose	9.5 (± 17.25)	17.9 (± 25.31)		
8 weeks post-dose	6.8 (± 13.64)	16 (± 24.24)		
12 weeks post-dose	6.8 (± 12.92)	13 (± 19.77)		

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's assessment of Gout pain intensity in the most affected joint (Likert scale): Frequency table by timepoint and treatment

End point title	Patient's assessment of Gout pain intensity in the most affected joint (Likert scale): Frequency table by timepoint and treatment

End point description:

Patients will score their current pain intensity in the most affected joint of the gout flare on a 5-point Likert scale (none, mild, moderate, severe, extreme).

End point type	Secondary

End point timeframe:

baseline through week 12

End point values	ACZ885 150 mg	Triamcinolone acetonide 40 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	69		
Units: participants				
baseline none	0	0		
baseline mild	2	3		
baseline moderate	25	18		
baseline severe	37	44		
baseline extreme	3	4		
6 hours post-dose none	0	0		
6 hours post-dose mild	18	14		
6 hours post-dose moderate	28	26		
6 hours post-dose severe	17	29		
6 hours post-dose extreme	2	0		
12 hours post-dose none	1	2		
12 hours post-dose mild	28	19		
12 hours post-dose moderate	28	26		
12 hours post-dose severe	7	21		
12 hours post-dose extreme	1	1		
24 hours post-dose none	3	4		

24 hours post-dose mild	40	20		
24 hours post-dose moderate	19	25		
24 hours post-dose severe	2	20		
24 hours post-dose extreme	1	0		
48 hours post-dose none	10	10		
48 hours post-dose mild	48	21		
48 hours post-dose moderate	7	20		
48 hours post-dose severe	2	14		
48 hours post-dose extreme	0	2		
72 hours post-dose none	14	12		
72 hours post-dose mild	45	26		
72 hours post-dose moderate	8	16		
72 hours post-dose severe	0	9		
72 hours post-dose extreme	0	4		
4 days post-dose none	21	14		
4 days post-dose mild	39	29		
4 days post-dose moderate	7	13		
4 days post-dose severe	0	10		
4 days post-dose extreme	0	0		
7 days post-dose none	32	23		
7 days post-dose mild	29	25		
7 days post-dose moderate	5	10		
7 days post-dose severe	1	8		
7 days post-dose extreme	0	0		
4 weeks post-dose none	43	24		
4 weeks post-dose mild	17	25		
4 weeks post-dose moderate	4	6		
4 weeks post-dose severe	1	0		
4 weeks post-dose extreme	0	0		
8 weeks post-dose none	39	30		
8 weeks post-dose mild	22	21		
8 weeks post-dose moderate	2	6		
8 weeks post-dose severe	2	2		
8 weeks post-dose extreme	0	0		
12 weeks post-dose none	41	25		
12 weeks post-dose mild	18	28		
12 weeks post-dose moderate	3	8		
12 weeks post-dose severe	2	1		
12 weeks post-dose extreme	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Patient’s global assessment of response to treatment: Frequency table by timepoint and treatment using a Likert scale.

End point title	Patient’s global assessment of response to treatment: Frequency table by timepoint and treatment using a Likert scale.

End point description:

Patients will score their response to pain on a 7-point Likert scale (excellent, good ,acceptable, slight,poor,very poor,not done).

End point type	Secondary

End point timeframe:

72 hours through week 12

End point values	ACZ885 150 mg	Triamcinolone acetonide 40 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	69		
Units: participants				
72 hours post-dose excellent	7	3		
72 hours post-dose good	40	17		
72 hours post-dose acceptable	14	18		
72 hours post-dose slight	4	11		
72 hours post-dose poor	1	10		
72 hours post-dose very poor	0	0		
72 hours post-dose not done	0	1		
7 days post-dose excellent	16	4		
7 days post-dose good	38	20		
7 days post-dose acceptable	9	18		
7 days post-dose slight	1	7		
7 days post-dose poor	1	16		
7 days post-dose very poor	0	0		
7 days post-dose not done	0	1		
4 weeks post-dose excellent	15	6		
4 weeks post-dose good	33	19		
4 weeks post-dose acceptable	13	14		
4 weeks post-dose slight	4	7		
4 weeks post-dose poor	0	9		
4 weeks post-dose very poor	0	0		
4 weeks post-dose not done	0	2		
8 weeks post-dose excellent	18	8		
8 weeks post-dose good	35	16		
8 weeks post-dose acceptable	10	18		
8 weeks post-dose slight	2	9		
8 weeks post-dose poor	0	8		
8 weeks post-dose very poor	0	0		
8 weeks post-dose not done	0	1		
12 weeks post-dose excellent	16	4		
12 weeks post-dose good	37	21		
12 weeks post-dose acceptable	10	21		
12 weeks post-dose slight	0	7		
12 weeks post-dose poor	1	9		
12 weeks post-dose very poor	0	0		
12 weeks post-dose not done	3	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Physician’s assessment of tenderness: Frequency table by timepoint and treatment

End point title	Physician’s assessment of tenderness: Frequency table by timepoint and treatment

End point description:

Physicians will score their response to pain on a 5-point Likert scale (no pain, pain,pain and winces,pain winces and withdraws and not assessed).

End point type	Secondary

End point timeframe:

baseline 72 hours,7 days 4 weeks, 8 weeks and 12 weeks post dose

End point values	ACZ885 150 mg	Triamcinolone acetonide 40 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	69		
Units: participants				
Baseline no pain	0	0		
Baseline pain	15	16		
Baseline pain and winces	31	29		
Baseline pain, winces and withdraws	21	24		
Baseline not assessed	0	0		
72 hours post-dose no pain	23	16		
72 hours post-dose pain	37	26		
72 hours post-dose pain and winces	5	11		
72 hours post-dose pain, winces and withdraws	1	3		
72 hours post-dose not assessed	0	0		
7 days post-dose no pain	41	26		
7 days post-dose pain	23	27		
7 days post-dose pain and winces	2	10		
7 days post-dose pain , winces and withdraws	0	2		
7 days post-dose not assessed	0	0		
4 weeks post-dose no pain	54	30		
4 weeks post-dose pain	10	19		
4 weeks post-dose pain and winces	1	3		
4 weeks post-dose pain, winces and withdraws	0	3		
4 weeks post-dose not assessed	0	0		
8 weeks post-dose no pain	54	38		

8 weeks post-dose pain	11	19		
8 weeks post-dose pain and winces	0	1		
8 weeks post-dose pain winces and withdraws	0	1		
8 weeks post-dose not assessed	0	0		
12 weeks post-dose no pain	53	39		
12 weeks post-dose pain	7	22		
12 weeks post-dose pain and winces	2	1		
12 weeks post-dose pain, winces and withdraws	2	0		
12 weeks post-dose not assessed	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Physician’s assessment of swelling: Frequency table by timepoint and treatment

End point title	Physician’s assessment of swelling: Frequency table by timepoint and treatment

End point description:

Physicians will score their response to pain on a 5-point Likert scale (no pain, pain,pain and winces,pain winces and withdraws and not assessed).

End point type	Secondary

End point timeframe:

baseline 72 hours,7 days 4 weeks, 8 weeks and 12 weeks post dose

End point values	ACZ885 150 mg	Triamcinolone acetonide 40 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	69		
Units: participants				
Baseline No swelling	1	3		
Baseline Palpable	13	12		
Baseline Visible	29	39		
Baseline Bulging beyond the joint margins	24	15		
Baseline not assessed	0	0		
72 hours post-dose No swelling	38	22		
72 hours post-dose Palpable	15	15		
72 hours post-dose Visible	12	18		
72 hrs post-dose Bulging beyond the joint margins	1	1		
72 hours post-dose not assessed	0	0		
7 days post-dose No swelling	53	35		
7 days post-dose Palpable	9	18		
7 days post-dose Visible	3	9		

7 days post-dose Bulging beyond the joint margins	1	3		
7 days post-dose not assessed0	0	0		
4 weeks post-dose No swelling	60	40		
4 weeks post-dose Palpable	2	9		
4 weeks post-dose Visible	3	4		
4 weeks post-dose Bulging beyond the joint margins	0	2		
4 weeks post-dose not assessed	0	0		
8 weeks post-dose No swelling	63	49		
8 weeks post-dose Palpable	0	6		
8 weeks post-dose Visible	2	4		
8 weeks post-dose Bulging beyond the joint margins	0	0		
8 weeks post-dose not assessed	0	0		
12 weeks post-dose No swelling	61	52		
12 weeks post-dose Palpable	1	6		
12 weeks post-dose Visible	2	2		
12 wks post-dose Bulging beyond the joint margins	0	2		
12 weeks post-dose not assessed	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Physician’s assessment of erythema: Frequency table by timepoint and treatment

End point title	Physician’s assessment of erythema: Frequency table by timepoint and treatment

End point description:

Physicians will score their response of erythema on a 4-point Likert scale (absent, present not assessed and not assessable).

End point type	Secondary

End point timeframe:

baseline 72 hours,7 days 4 weeks, 8 weeks and 12 weeks post dose

End point values	ACZ885 150 mg	Triamcinolone acetonide 40 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	69		
Units: participants				
Baseline Absent	19	19		
Baseline present	48	50		
Baseline not assessed	0	0		
Baseline not assessable	0	0		
72 hours post-dose absent	54	41		
72 hours post-dose present	11	15		

72 hours post-dose not assessed	0	0		
72 hrs post-dose not assessable	1	0		
7 days post-dose absent	62	57		
7 days post-dose present	3	8		
7 days post-dose not assessed	0	0		
7 days post-dose not assessable	1	0		
4 weeks post-dose absent	63	49		
4 weeks post-dose present	1	6		
4 weeks post-dose not assessed	0	0		
4 weeks post-dose not assessable	1	0		
8 weeks post-dose absent	65	56		
8 weeks post-dose present	0	3		
8 weeks post-dose not assessed	0	0		
8 weeks post-dose not assessable	0	0		
12 weeks post-dose absent	62	61		
12 weeks post-dose present	1	1		
12 weeks post-dose not assessed	0	0		
12 wks post-dose not assessable	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Physician’s assessment of range of motion: Frequency table by timepoint and treatment

End point title	Physician’s assessment of range of motion: Frequency table by timepoint and treatment

End point description:

Physicians will score their response ofrange of motion on a 5-point Likert scale (normal,mildly restricted, moderately restricted, severely restricted and immolbilized).

End point type	Secondary

End point timeframe:

baseline through week 12

End point values	ACZ885 150 mg	Triamcinolone acetonide 40 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	69		
Units: participants				
baseline normal	0	0		
baseline mildly restricted	3	6		
baseline moderately restricted	32	24		
baseline severely restricted	27	39		
baseline immobilzed	5	0		
72 hours post-dose normal	20	15		
72 hours post-dose mildly restricted	33	19		

72 hours post-dose moderately restricted	11	14		
72 hours post-dose severely restricted	2	7		
72 hours post-dose immobilized	0	1		
7 days post-dose normal	35	26		
7 days post-dose mildly restricted	25	20		
7 days post-dose moderately restricted	4	15		
7 days post-dose severely restricted	1	3		
7 days post-dose immobilized	0	1		
4 weeks post-dose normal	49	25		
4 weeks post-dose mildly restricted	12	22		
4 weeks post-dose moderately restricted	3	7		
4 weeks post-dose severely restricted	1	1		
4 weeks post-dose immobilized	0	0		
8 weeks post-dose normal	51	32		
8 weeks post-dose mildly restricted	12	18		
8 weeks post-dose moderately restricted	1	6		
8 weeks post-dose severely restricted	1	3		
8 weeks post-dose immobilized	0	0		
12 weeks post-dose normal	50	30		
12 weeks post-dose mildly restrcted	1	23		
12 weeks post-dose moderately restricted	2	6		
12 weeks post-dose severely restricted	1	3		
12 weeks post-dose immobilized	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to at least a 50% reduction in baseline pain intensity: Survival analysis by treatment

End point title	Time to at least a 50% reduction in baseline pain intensity: Survival analysis by treatment
End point description: Kaplan Meier estimate	
End point type	Secondary
End point timeframe: 12 weeks	

End point values	ACZ885 150 mg	Triamcinolone acetonide 40 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	69		
Units: hours				
median (confidence interval 95%)	24 (24 to 48)	48 (24 to 72)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to complete resolution of pain: Survival analysis by treatment

End point title	Time to complete resolution of pain: Survival analysis by treatment
End point description: Kaplan Meier estimate	
End point type	Secondary
End point timeframe: 12 weeks	

End point values	ACZ885 150 mg	Triamcinolone acetonide 40 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	69		
Units: hours				
median (confidence interval 95%)	168 (120 to 168)	168 (99 to 999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to first rescue medication intake

End point title	Time to first rescue medication intake
End point description:	
End point type	Secondary
End point timeframe: 12 weeks	

End point values	ACZ885 150 mg	Triamcinolone acetonide 40 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	69		
Units: hours				
arithmetic mean (standard deviation)	31.8 (± 30.45)	41.5 (± 38.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: percent patients who took rescue medication

End point title	percent patients who took rescue medication

End point description:

End point type	Secondary

End point timeframe:

12 weeks

End point values	ACZ885 150 mg	Triamcinolone acetonide 40 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	69		
Units: percentage				
number (not applicable)				
Baseline flare (n= 29,42)	43.3	60.9		
Last post-baseline flare (n=3,4)	75	44.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Amount of rescue medication taken at baseline flare and post baseline flare.

End point title	Amount of rescue medication taken at baseline flare and post baseline flare.

End point description:

Paracetamol / acetaminophen, Prednisolone and Prednisone taken at baseline flare and post baseline flare.

End point type	Secondary

End point timeframe:

12 weeks

End point values	ACZ885 150 mg	Triamcinolone acetonide 40 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	69		
Units: mg				
arithmetic mean (standard deviation)				
Baseline flare Paracetamol / acetaminophen	342.5 (± 680.53)	451.4 (± 744.19)		
Baseline flare Prednisolol	1.1 (± 4.25)	5 (± 15.29)		
Baseline Flare Prednisone	0.7 (± 5.52)	5.2 (± 30.42)		
Baseline flare Codeine	0 (± 0)	0.4 (± 3.61)		
Last post-baseline flare Paraceta/acetamin n=4,9	287.5 (± 337.58)	222.2 (± 666.67)		
Last post-baseline flare Prednisolone n=4,9	5 (± 10)	4.4 (± 8.82)		
Last post-baseline flare Prednisone n=4,9	0 (± 0)	0.6 (± 1.67)		

Statistical analyses

No statistical analyses for this end point

Secondary: To evaluate the efficacy of canakinumab with regards to inflammatory markers (high sensitivity C-reactive protein [hsCRP]) measured in the serum at 72 hours post dose

End point title	To evaluate the efficacy of canakinumab with regards to inflammatory markers (high sensitivity C-reactive protein [hsCRP]) measured in the serum at 72 hours post dose

End point description:

End point type	Secondary

End point timeframe:

72 hours post dose

End point values	ACZ885 150 mg	Triamcinolone acetonide 40 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	69		
Units: mg/L				
number (confidence interval 95%)	5.5 (4.4 to 6.9)	7.2 (5.7 to 9.2)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse Events are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All Adverse events are reported in this record from First Patient First Treatment until Last Patient Last Visit.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18

Reporting groups

Reporting group title	ACZ885 150mg sc

Reporting group description:

ACZ885 150mg sc

Reporting group title	Triam 40mg im

Reporting group description:

Triam 40mg im

Serious adverse events	ACZ885 150mg sc	Triam 40mg im	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 67 (0.00%)	1 / 69 (1.45%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Hepatobiliary disorders			
Hepatic function abnormal			
alternative dictionary used: MedDRA 18			
subjects affected / exposed	0 / 67 (0.00%)	1 / 69 (1.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Gouty arthritis			
alternative dictionary used: MedDRA 18			
subjects affected / exposed	0 / 67 (0.00%)	1 / 69 (1.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	ACZ885 150mg sc	Triam 40mg im	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 67 (0.00%)	4 / 69 (5.80%)	
Vascular disorders			
Hypertension			
alternative dictionary used: MedDRA 18			
subjects affected / exposed	0 / 67 (0.00%)	4 / 69 (5.80%)	
occurrences (all)	0	4	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 April 2011	This amendment (Amendment 1, issued on 13-Apr-2011, before study start) rendered pre-screening for HIV, Hepatitis, TB and diabetes as mandatory in order to verify exclusion criteria prior to randomization and minimize the risk of protocol deviations

Notes:

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.

This study was terminated early for strategic reasons, not concerns for efficacy or safety of canakinumab.
Due to EudraCT system limitations, data using 999 as data points in this record are not an accurate representation of clinical trial results.

Notes: