ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
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ClinicalTrials.gov ID: NCT00977106

Study Identification

Unique Protocol ID:	ML22017
Brief Title:	TORPEDO Study: A Study on Rapid Effect of Tocilizumab in Patients With Rheumatoid Arthritis With an Inadequate Response to Disease-Modifying Antirheumatic Drugs (DMARDs) or Anti-TNF
Official Title:	Comparative Double Blind Placebo Controlled Clinical Study on Tocilizumab Rapid Efficacy on Patients Relief in rheumatoïd Arthritis With an Inadequate Response to DMARDs or Anti TNF :TORPEDO
Secondary IDs:	2008-008309-23

Study Status

Record Verification:	September 2014
Overall Status:	Completed
Study Start:	June 2009
Primary Completion:	October 2011 [Actual]
Study Completion:	October 2011 [Actual]

Sponsor/Collaborators

Sponsor:	Hoffmann-La Roche
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No

IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 2009/29 Board Name: Sud-Ouest et Outre Mer III Board Affiliation: Unknown Phone: +33 5 57817607 Email: cpp.soom3@u-bordeaux2.fr
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)

Study Description

Brief Summary:	This study will assess the onset and maintenance of effect of tocilizumab on relief in patients with active moderate or severe rheumatoid arthritis who have had an inadequate response to DMARDs or anti-TNF. For the first, double-blind, part of the study patients will be randomized to receive an iv infusion of either 8mg/kg tocilizumab or placebo. After 4 weeks this will be followed by 11 months treatment with tocilizumab 8mg/kg iv infusion every 4 weeks. Methotrexate or DMARD therapy will be continued throughout study treatment. Target sample size is >100.
Detailed Description:	

Conditions

Conditions:	Rheumatoid Arthritis
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	3
Masking:	Double Blind (Subject, Investigator)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study

Enrollment: 103 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1	Drug: tocilizumab [RoActemra/Actemra] single iv infusion 8 mg/kg
Placebo Comparator: 2	Drug: placebo single iv infusion
Experimental: 3	Drug: tocilizumab [RoActemra/Actemra] iv infusion 8mg/kg every 4 weeks for 11 months

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- adult patients >/= 18 years of age
- active moderate or severe rheumatoid arthritis of <10 years duration with inadequate response to methotrexate or anti-TNF
- on methotrexate treatment for at least 10 weeks, at least 8 weeks on stable dose
- patients receiving oral corticosteroids and/or NSAIDs should be at stable dose for 4 weeks

Exclusion Criteria:

- rheumatic autoimmune disease other than RA, or significant systemic involvement secondary to RA
- functional class IV by ACR classification
- history of inflammatory joint disease other than RA
- previous treatment with cell-depleting therapies, abatacept or rituximab
- active current or history of recurrent infection, or any major episode of infection requiring hospitalization or treatment with iv antibiotics <4 weeks or oral antibiotics <2 weeks prior to screening

Contacts/Locations

Study Officials: Clinical Trials
Study Director
Hoffmann-La Roche

Locations: France
Bordeaux, France, 33076

Paris, France, 75679

Paris, France, 75679

St Priest En Jarez, France, 42277

Orleans, France, 45000

Amiens, France, 80054

Nantes, France, 44035

La Roche Sur Yon, France, 85925

Paris, France, 75877

Limoges, France, 87042

Rennes, France, 35203

Bois Guillaume, France, 76233

Paris, France, 75651

Echirolles, France, 38434

Chambray Les Tours, France, 37171

Bayonne, France, 64109

Clermont-ferrand, France, 63003

Lyon, France, 69437

Amiens, France, 80094

Metz, France, 57077

Cahors, France, 46005

Toulouse, France, 31059

Brest, France, 29609

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) intravenously (IV) during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 milligrams per kilogram (mg/kg; 800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Overall Study

	Placebo, Tocilizumab	Tocilizumab
Started	47	56 [1]
Completed	37	45
Not Completed	10	11
Adverse Event	5	6
Withdrawal by Subject	2	2
Lack of Efficacy	2	2

	Placebo, Tocilizumab	Tocilizumab
Protocol Violation	0	1
Not specified	1	0

[1] Includes 3 participants who were randomized to placebo, but received tocilizumab.

Baseline Characteristics

Analysis Population Description

Intent-to-treat (ITT) population: all randomized participants who received at least 1 treatment infusion (completed or not). Three participants were randomized to the Placebo treatment group but received tocilizumab.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Baseline Measures

	Placebo, Tocilizumab	Tocilizumab	Total
Number of Participants	50	53	103
Age, Continuous [units: years] Mean (Standard Deviation)	51.3 (11.8)	52.8 (11.6)	52.0 (11.6)
Gender, Male/Female [units: participants]			
Female	36	41	77
Male	14	12	26

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants With Clinically Significant Improvement in Health Assessment Questionnaire - Disability Index (HAQ-DI) at Week 4

Measure Description	HAQ-DI includes 20 questions concerning participant's activities of daily life, grouped in 8 scales of 2 to 3 questions for each activity. To respond to each question, a four-level response (score of 0 to 3 points), with higher scores showing larger functional limitations, was chosen. Scoring was as follows with respect to performance of participant's everyday activities: 0 (equals)=without difficulties; 1= with some difficulties; 2=with great difficulties; and 3=unable to perform these actions at all. Minimum score was 0, maximum score was 3. Relevant clinical improvement was defined as a reduction of at least 0.22 points in HAQ-DI.
Time Frame	Week 4
Safety Issue?	No

Analysis Population Description
ITT Population

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
Percentage of Participants With Clinically Significant Improvement in Health Assessment Questionnaire - Disability Index (HAQ-DI) at Week 4 [units: percentage of participants]	42.0	49.1

Statistical Analysis 1 for Percentage of Participants With Clinically Significant Improvement in Health Assessment Questionnaire - Disability Index (HAQ-DI) at Week 4

Statistical Analysis Overview	Comparison Groups	Placebo, Tocilizumab, Tocilizumab
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.472
	Comments	[Not specified]
	Method	Chi-squared
	Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Patient Global Assessment of Disease Activity During the Double-Blind Treatment Period
Measure Description	Participants were asked to rate their assessment of disease activity using a visual analog scale (VAS) of 0 to 100 millimeters (mm), where 0 represented no symptoms and 100 represented severe symptoms. Participants were asked to mark the line corresponding to their assessment and the distance from the left edge was measured. A negative value in change from Baseline indicates an improvement.
Time Frame	Baseline, Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; number (n) = number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
Patient Global Assessment of Disease Activity During the Double-Blind Treatment Period [units: mm] Mean (Standard Deviation)		
Baseline (n=50,53)	58.8 (21.1)	64.3 (17.4)
Week 1 (n=42,42)	49.0 (23.2)	54.2 (20.6)

	Placebo, Tocilizumab	Tocilizumab
Change at Week 1 (n=42,42)	-11.0 (19.7)	-7.4 (17.8)
Week 4 (n=45,51)	49.2 (24.0)	51.1 (22.7)
Change at Week 4 (n=45,51)	-14.3 (23.6)	-9.6 (17.4)

Statistical Analysis 1 for Patient Global Assessment of Disease Activity During the Double-Blind Treatment Period

Statistical Analysis Overview	Comparison Groups	Placebo, Tocilizumab, Tocilizumab
	Comments	Change at Week 1
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.377
	Comments	Between-group test (equal variances)
	Method	Other [Student t-test]
	Comments	[Not specified]

Statistical Analysis 2 for Patient Global Assessment of Disease Activity During the Double-Blind Treatment Period

Statistical Analysis Overview	Comparison Groups	Placebo, Tocilizumab, Tocilizumab
	Comments	Change at Week 4
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.276
	Comments	[Not specified]
	Method	Other [Student t-test]
	Comments	Between-group test (unequal variances)

3. Secondary Outcome Measure:

Measure Title	Patient Global Assessment of Disease Activity During the Open Treatment Period

Measure Description	Participants were asked to rate their assessment of disease activity using a VAS of 0 to 100 mm, where 0 represented no symptoms and 100 represented severe symptoms. Participants were asked to mark the line corresponding to their assessment and the distance from the left edge was measured. A negative value in change from Baseline indicates an improvement.
Time Frame	Baseline, Weeks 12, 24, 36 and 48
Safety Issue?	No

Analysis Population Description

ITT Population; 3 participants were randomized to the placebo treatment group but received tocilizumab. n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	47	56
Patient Global Assessment of Disease Activity During the Open Treatment Period [units: mm] Mean (Standard Deviation)		
Baseline (n=46,56)	51.2 (22.9)	59.4 (21.1)
Week 12 (n=45,51)	36.0 (23.8)	32.7 (24.7)
Change at Week 12 (n=44,51)	-16.2 (27.6)	-26.7 (24.2)
Week 24 (n=438,48)	27.4 (21.7)	31.4 (25.9)
Change at Week 24 (n=42,48)	-25.3 (28.5)	-27.2 (24.5)
Week 36 (n=39,46)	25.7 (18.1)	28.7 (24.5)
Change at Week 36 (n=38,46)	-24.2 (27.8)	-29.7 (25.9)
Week 48 (n=36,45)	25.6 (24.4)	26.6 (23.2)
Change at Week 48 (n=35,45)	-24.9 (28.5)	-31.7 (23.3)

4. Secondary Outcome Measure:

Measure Title	Physician Global Assessment of Disease Activity During the Double-Blind Treatment Period
Measure Description	Physicians were asked to assess disease activity of the participants using a VAS of 0 to 100 mm, where 0 represented no symptoms and 100 represented severe symptoms. Physicians were asked to mark the line corresponding to their assessment and the distance from the left edge was measured. A negative value in change from Baseline indicates an improvement.
Time Frame	Baseline and Week 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
Physician Global Assessment of Disease Activity During the Double-Blind Treatment Period [units: mm] Mean (Standard Deviation)		
Baseline (n=50,53)	60.8 (17.2)	58.4 (15.3)
Week 4 (n=50,52)	49.2 (18.1)	44.6 (22.5)
Change at Week 4 (n=50,52)	-11.6 (19.3)	-14.3 (20.7)

Statistical Analysis 1 for Physician Global Assessment of Disease Activity During the Double-Blind Treatment Period

Statistical Analysis Overview	Comparison Groups	Placebo, Tocilizumab, Tocilizumab
	Comments	Change at Week 4
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.502
	Comments	[Not specified]
	Method	Other [Student t-test]
	Comments	Between-group test (equal variances)

5. Secondary Outcome Measure:

Measure Title	Physician Global Assessment of Disease Activity During the Open Treatment Period
Measure Description	Physicians were asked to assess disease activity of the participants using a VAS of 0 to 100 mm, where 0 represented no symptoms and 100 represented severe symptoms. Physicians were asked to mark the line corresponding to their assessment and the distance from the left edge was measured. A negative value in change from Baseline indicates an improvement.
Time Frame	Baseline, Weeks 12, 24, 36, and 48
Safety Issue?	No

Analysis Population Description

ITT Population; 3 participants were randomized to the placebo treatment group but received tocilizumab. n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	47	56
Physician Global Assessment of Disease Activity During the Open Treatment Period [units: mm] Mean (Standard Deviation)		
Baseline (n=47,56)	49.3 (18.6)	59.6 (16.3)
Week 12 (n=44,51)	32.9 (20.4)	28.3 (21.7)
Change at Week 12 (n=44,51)	-16.5 (23.9)	-30.8 (21.7)
Week 24 (n=42,50)	24.3 (17.0)	24.7 (21.1)
Change at Week 24 (n=42,50)	-27.4 (21.3)	-34.9 (21.3)
Week 36 (n=38,46)	22.7 (16.5)	23.1 (20.6)
Change at Week 36 (n=38,46)	-28.4 (20.7)	-34.9 (23.1)
Week 48 (n=37,44)	16.4 (15.8)	19.3 (18.2)
Change at Week 48 (n=37,44)	-35.0 (23.0)	-39.4 (19.7)

6. Secondary Outcome Measure:

Measure Title	Patient Global Assessment of Pain During the Double-Blind Treatment Period
Measure Description	Participants were asked to rate their assessment of pain using a VAS of 0 to 100 mm, where 0 represented no pain and 100 represented intolerable pain. Participants were asked to mark the line corresponding to their assessment and the distance from the left edge was measured. A negative value in change from Baseline indicates an improvement.
Time Frame	Baseline and Week 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
Patient Global Assessment of Pain During the Double-Blind Treatment Period [units: mm] Mean (Standard Deviation)		
Baseline (n=49,51)	60.2 (20.0)	54.6 (21.8)
Week 4 (n=49,53)	49.1 (24.6)	46.4 (27.0)
Change at Week 4 (n=49,51)	-11.1 (25.6)	-7.3 (22.8)

Statistical Analysis 1 for Patient Global Assessment of Pain During the Double-Blind Treatment Period

Statistical Analysis Overview	Comparison Groups	Placebo, Tocilizumab, Tocilizumab
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.434
	Comments	Between placebo and TCZ groups test (Equal Variances) at week 4
	Method	t-test, 1 sided
	Comments	[Not specified]

7. Secondary Outcome Measure:

Measure Title	Patient Global Assessment of Pain During the Open Treatment Period

Measure Description	Participants were asked to rate their assessment of pain using a VAS of 0 to 100 mm, where 0 represented no pain and 100 represented intolerable pain. Participants were asked to mark the line corresponding to their assessment and the distance from the left edge was measured. A negative value in change from Baseline indicates an improvement.
Time Frame	Baseline and Weeks 12, 24, 36, and 48
Safety Issue?	No

Analysis Population Description

ITT Population; 3 participants were randomized to the placebo treatment group but received tocilizumab. n=number of participants assessed at a specific visit

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	47	56
Patient Global Assessment of Pain During the Open Treatment Period [units: mm] Mean (Standard Deviation)		
Baseline (n=46,54)	48.9 (24.5)	55.1 (22.2)
Week 12 (n=45,51)	29.6 (23.9)	32.8 (24.0)
Change at Week 12 (n=44,50)	-20.3 (27.6)	-22.2 (26.2)
Week 24 (n=43,50)	26.2 (21.3)	27.7 (25.2)
Change at Week 24 (n=42,49)	-25.0 (29.2)	-25.9 (22.0)
Week 36 (n=39,46)	23.1 (17.2)	25.0 (21.3)
Change at Week 36 (n=38,45)	-25.6 (31.0)	-28.3 (27.4)
Week 48 (n=36,45)	22.1 (22.9)	23.0 (20.4)
Change at Week 48 (n=35,44)	-28.0 (29.7)	-30.4 (25.8)

8. Secondary Outcome Measure:

Measure Title	Synovitis Score During the Double-Blind Treatment Period Assessed Using B-Mode Ultrasound
Measure Description	Synovitis was assessed by ultrasonography (B-mode ultrasound and Power Doppler) and scored from “0” to “3”, for each of 40 joints (5 metacarpal phalangeal [MCP; left and right] joints, 5 proximal interphalangeal [PIP; left and right] joints, left and right wrists, elbows, shoulders, knees, and ankles, and 5 metatarsal phalangeal [MTP; left and right] joints); synovitis scores were calculated by adding the sum of scores for each joint for a total score ranging from 0 to 120. A score of 0 indicated no damage and a score of 120 indicated most severe damage. Baseline = Last available value before Day 0 (screening or Day 0) for participants with first tocilizumab infusion at Day 0 and last value available before Week 4 (Week 1 or Week 4) for participants with first tocilizumab infusion at Week 4. A negative change from baseline indicated improvement.
Time Frame	Baseline, Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
Synovitis Score During the Double-Blind Treatment Period Assessed Using B-Mode Ultrasound [units: units on a scale] Mean (Standard Deviation)		
Baseline (n=50,53)	26.4 (17.2)	25.8 (16.8)
Week 1 (n=49,53)	26.4 (19.1)	25.3 (17.6)
Change at Week 1 (n=49,53)	-0.1 (7.1)	-0.6 (7.1)

	Placebo, Tocilizumab	Tocilizumab
Week 4 (n=48,52)	26.3 (18.9)	21.8 (15.5)
Change at Week 4 (n=48,52)	0.8 (7.8)	-4.4 (10.0)

Statistical Analysis 1 for Synovitis Score During the Double-Blind Treatment Period Assessed Using B-Mode Ultrasound

Statistical Analysis Overview	Comparison Groups	Placebo, Tocilizumab, Tocilizumab
	Comments	Change at Week 1
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.692
	Comments	[Not specified]
	Method	Wilcoxon (Mann-Whitney)
	Comments	[Not specified]

Statistical Analysis 2 for Synovitis Score During the Double-Blind Treatment Period Assessed Using B-Mode Ultrasound

Statistical Analysis Overview	Comparison Groups	Placebo, Tocilizumab, Tocilizumab
	Comments	Change at Week 4
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.019
	Comments	[Not specified]
	Method	Wilcoxon (Mann-Whitney)
	Comments	[Not specified]

9. Secondary Outcome Measure:

Measure Title	Synovitis Score During the Double-Blind Treatment Period Assessed Using Power Doppler Ultrasound

Measure Description	Synovitis was assessed by ultrasonography (B-mode ultrasound and Power Doppler) and scored from “0” to “3”, for each of 40 joints (5 MCP [left and right] joints, 5 PIP [left and right] joints, left and right wrists, elbows, shoulders, knees, and ankles, and 5 MTP [left and right] joints); synovitis scores were calculated by adding the sum of scores for each joint for a total score ranging from 0 to 120 (higher score=more severe disease). Baseline = Last available value before Day 0 (screening or Day 0) for participants with first tocilizumab infusion at Day 0 and last value available before Week 4 (Week 1 or Week 4) for participants with first tocilizumab infusion at Week 4. Negative change from baseline indicated improvement.
Time Frame	Baseline, Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
Synovitis Score During the Double-Blind Treatment Period Assessed Using Power Doppler Ultrasound [units: units on a scale] Mean (Standard Deviation)		
Baseline (n=50,53)	10.1 (11.2)	10.2 (11.4)
Week 1 (n=49,53)	9.6 (11.9)	8.9 (12.3)
Change at Week 1 (n=49,53)	-0.3 (3.5)	-1.4 (4.9)
Week 4 (n=48,52)	10.0 (13.2)	8.4 (12.1)
Change at Week 4 (n=48,52)	0.8 (7.7)	-2.0 (5.1)

Statistical Analysis 1 for Synovitis Score During the Double-Blind Treatment Period Assessed Using Power Doppler Ultrasound

Statistical Analysis Overview	Comparison Groups	Placebo, Tocilizumab, Tocilizumab
	Comments	Change at Week 1
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.137
	Comments	[Not specified]
	Method	Wilcoxon (Mann-Whitney)
	Comments	[Not specified]

Statistical Analysis 2 for Synovitis Score During the Double-Blind Treatment Period Assessed Using Power Doppler Ultrasound

Statistical Analysis Overview	Comparison Groups	Placebo, Tocilizumab, Tocilizumab
	Comments	Change at Week 4
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.043
	Comments	[Not specified]
	Method	Wilcoxon (Mann-Whitney)
	Comments	[Not specified]

10. Secondary Outcome Measure:

Measure Title	Percent Change From Baseline in Synovitis Score During the Open Treatment Period Assessed Using B-Mode Ultrasound
Measure Description	Synovitis was assessed by ultrasonography (B-mode ultrasound and Power Doppler) and scored from “0” to “3”, for each of 40 joints (5 MCP [left and right] joints, 5 PIP [left and right] joints, left and right wrists, elbows, shoulders, knees, and ankles, and 5 MTP [left and right] joints); synovitis scores were calculated by adding the sum of scores for each joint for a total score ranging from 0 to 120 (higher score=more severe disease). Baseline = Last available value before Day 0 (screening or Day 0) for participants with first tocilizumab infusion at Day 0 and last value available before Week 4 (Week 1 or Week 4) for participants with first tocilizumab infusion at Week 4. Relative change was the percentage (%) change from baseline.

Time Frame	Weeks 12, 24, and 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population: all randomized participants with at least 1 tocilizumab infusion (completed or not). n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilizumab
Number of Participants Analyzed	94
Percent Change From Baseline in Synovitis Score During the Open Treatment Period Assessed Using B-Mode Ultrasound [units: percent change] Mean (Standard Deviation)	
Week 12 (n=94)	-15.0 (81.9)
Week 24 (n=87)	-30.5 (64.4)
Week 48 (n=77)	-43.7 (67.0)

11. Secondary Outcome Measure:

Measure Title	Percent Change From Baseline in Synovitis Score During the Open Treatment Period Assessed Using Power Doppler Ultrasound
Measure Description	Synovitis was assessed by ultrasonography (B-mode ultrasound and Power Doppler) and scored from “0” to “3”, for each of 40 joints (5 MCP [left and right] joints, 5 PIP [left and right] joints, left and right wrists, elbows, shoulders, knees, and ankles, and 5 MTP [left and right] joints); synovitis scores were calculated by adding the sum of scores for each joint for a total score ranging from 0 to 120 (higher score=more severe disease). Baseline = Last available value before Day 0 (screening or Day 0) for participants with first tocilizumab infusion at Day 0 and last value available before Week 4 (Week 1 or Week 4) for participants with first tocilizumab infusion at Week 4. Relative change was the percentage change from baseline.

Time Frame	Weeks 12, 24, and 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population: all randomized participants with at least 1 tocilizumab infusion (completed or not). n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilizumab
Number of Participants Analyzed	94
Percent Change From Baseline in Synovitis Score During the Open Treatment Period Assessed Using Power Doppler Ultrasound [units: percent change] Mean (Standard Deviation)	
Week 12 (n=94)	121.0 (573.0)
Week 24 (n=87)	-23.5 (92.8)
Week 48 (n=77)	3.6 (263.2)

12. Secondary Outcome Measure:

Measure Title	Erythrocyte Sedimentation Rate During the Double-Blind Treatment Period
Measure Description	Erythrocyte sedimentation rate is a biological marker of inflammation, measured in mm per hour (mm/hr). A reduction in ESR indicates improvement.
Time Frame	Baseline, Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
Erythrocyte Sedimentation Rate During the Double-Blind Treatment Period [units: mm/hr] Mean (Standard Deviation)		
Baseline (n=50,53)	27.5 (22.9)	28.1 (25.6)
Week 1 (n=49,51)	27.6 (24.2)	11.9 (12.7)
Week 4 (n=50,51)	26.6 (19.9)	8.2 (11.0)

13. Secondary Outcome Measure:

Measure Title	Percent Change From Baseline in Erythrocyte Sedimentation Rate During the Double-Blind Treatment
Measure Description	Erythrocyte sedimentation rate is a biological marker of inflammation. A negative change indicates improvement.
Time Frame	Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	49	53
Percent Change From Baseline in Erythrocyte Sedimentation Rate During the Double-Blind Treatment [units: percent change] Mean (Standard Deviation)		
Week 1 (n=49,53)	8.7 (56.4)	-51.2 (32.8)
Week 4 (n=48,52)	11.5 (64.1)	-65.9 (28.4)

14. Secondary Outcome Measure:

Measure Title	Erythrocyte Sedimentation Rate During the Open Treatment Period
Measure Description	Erythrocyte sedimentation rate is a biological marker of inflammation, measured in mm/hr. A reduction in ESR indicates improvement. Baseline = Last available value before Day 0 (screening or Day 0) for participants with first tocilizumab infusion at Day 0 and last value available before Week 4 (Week 1 or Week 4) for participants with first tocilizumab infusion at Week 4.
Time Frame	Baseline, Weeks 12, 24, 36, and 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilizumab
Number of Participants Analyzed	103
Erythrocyte Sedimentation Rate During the Open Treatment Period [units: mm/hr] Mean (Standard Deviation)	
Baseline (n=103)	27.8 (22.8)
Week 12 (n=96)	6.8 (11.4)
Week 24 (n=92)	5.9 (6.1)
Week 36 (n=84)	8.0 (13.4)
Week 48 (n=80)	4.6 (3.5)

15. Secondary Outcome Measure:

Measure Title	C-Reactive Protein During the Double-Blind Treatment Period
Measure Description	C-Reactive protein (CRP) is a biological marker of inflammation and is measured in nanograms per milliliter (ng/mL). A reduction in CRP indicates improvement.
Time Frame	Baseline, Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	48	53
C-Reactive Protein During the Double-Blind Treatment Period [units: ng/mL] Mean (Standard Deviation)		
Baseline (n=47,53)	18.6 (23.6)	14.2 (21.8)
Week 1 (n=47,52)	20.4 (34.3)	2.3 (2.0)
Week 4 (n=48,52)	17.5 (21.8)	3.8 (9.4)

16. Secondary Outcome Measure:

Measure Title	Percent Change From Baseline in C-Reactive Protein During the Double-Blind Treatment Period
Measure Description	C-Reactive protein (CRP) is a biological marker of inflammation. Negative changes from baseline indicate improvement.
Time Frame	Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	46	52
Percent Change From Baseline in C-Reactive Protein During the Double-Blind Treatment Period [units: percent change] Mean (Standard Deviation)		
Week 1 (n=44,52)	19.2 (70.1)	-66.2 (31.8)
Week 4 (n=46,52)	18.3 (95.6)	-47.0 (95.9)

17. Secondary Outcome Measure:

Measure Title	C- Reactive Protein During the Open Treatment Period
Measure Description	C-reactive protein is a biological marker of inflammation and is measured in nanograms per milliliter (ng/mL). Baseline = Last available value before Day 0 (screening or Day 0) for participants with first tocilizumab infusion at Day 0 and last value available before Week 4 (Week 1 or Week 4) for participants with first tocilizumab infusion at Week 4.
Time Frame	Baseline, Weeks 12, 24, 36, and 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilzumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilzumab
Number of Participants Analyzed	102
C- Reactive Protein During the Open Treatment Period [units: ng/L] Mean (Standard Deviation)	
Baseline (n=102)	15.8 (20.8)
Week 12 (n=95)	3.9 (9.7)
Week 24 (n=92)	3.2 (5.2)
Week 36 (n=80)	3.9 (6.6)
Week 48 (n=81)	2.6 (2.6)

18. Secondary Outcome Measure:

Measure Title	Serum Amyloid A Component During the Double-Blind Treatment Period
Measure Description	Serum Amyloid A (SAA) component is a biological marker of inflammation and is measured in mg/L. A reduction in SAA indicates improvement.
Time Frame	Baseline, Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	26	29
Serum Amyloid A Component During the Double-Blind Treatment Period [units: mg/L] Mean (Standard Deviation)		
Baseline (n=23,32)	72.0 (221.9)	57.9 (108.2)
Week 1 (n=26,29)	89.5 (271.2)	6.7 (3.6)
Week 4 (n=25,27)	61.2 (169.2)	8.9 (10.4)

19. Secondary Outcome Measure:

Measure Title	Percent Change From Baseline in Serum Amyloid A Component During the Double-Blind Treatment Period
Measure Description	Serum Amyloid A (SAA) component is a biological marker of inflammation. A negative change from baseline indicates improvement.
Time Frame	Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	22	28

	Placebo, Tocilizumab	Tocilizumab
Percent Change From Baseline in Serum Amyloid A Component During the Double-Blind Treatment Period [units: percent change] Mean (Standard Deviation)		
Week 1 (n=22,28)	59.5 (247.9)	-41.2 (61.3)
Week 4 (n=21,26)	-5.8 (39.3)	-35.5 (61.0)

20. Secondary Outcome Measure:

Measure Title	Serum Amyloid A Component During the Open Treatment Period
Measure Description	Serum Amyloid A (SAA) component is a biological marker of inflammation measured in mg/L. Baseline = Last available value before Day 0 (screening or Day 0) for participants with first tocilizumab infusion at Day 0 and last value available before Week 4 (Week 1 or Week 4) for participants with first tocilizumab infusion at Week 4.
Time Frame	Baseline, Weeks 12, 24, 36, and 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilzumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilzumab
Number of Participants Analyzed	58
Serum Amyloid A Component During the Open Treatment Period [units: mg/L] Mean (Standard Deviation)	
Baseline (n=58)	58.6 (135.9)

	Placebo, Tocilzumab
Week 12 (n=46)	40.3 (218.7)
Week 24 (n=46)	13.3 (41.6)
Week 36 (n=38)	7.3 (6.3)
Week 48 (n=37)	5.7 (3.0)

21. Secondary Outcome Measure:

Measure Title	Beta 2 Microglobulin Levels During the Open Treatment Period
Measure Description	Beta 2 Microglobulin is a biological marker of inflammation measured in micrograms per milliliter (mcg/mL). Baseline = Last available value before Day 0 (screening or Day 0) for participants with first tocilizumab infusion at Day 0 and last value available before Week 4 (Week 1 or Week 4) for participants with first tocilizumab infusion at Week 4.
Time Frame	Baseline, Weeks 12, 24, 36, and 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population;n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilzumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilzumab
Number of Participants Analyzed	96
Beta 2 Microglobulin Levels During the Open Treatment Period [units: mcg/mL] Mean (Standard Deviation)	
Baseline (n=96)	2.0 (0.6)
Week 12 (n=87)	2.0 (0.6)

	Placebo, Tocilzumab
Week 24 (n=78)	1.9 (0.6)
Week 36 (n=69)	2.0 (0.5)
Week 48 (n=64)	1.9 (0.5)

22. Secondary Outcome Measure:

Measure Title	Beta 2 Microglobulin Levels During the Double-Blind Treatment Period
Measure Description	Beta 2 Microglobulin is a biological marker of inflammation measured in micrograms per milliliter (mcg/mL).
Time Frame	Baseline, Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	45	49
Beta 2 Microglobulin Levels During the Double-Blind Treatment Period [units: mg/L] Mean (Standard Deviation)		
Baseline (n=39,49)	2.0 (0.6)	2.0 (0.6)
Week 1 (n=45,48)	2.0 (0.5)	2.1 (0.7)
Week 4 (n=45,47)	2.0 (0.5)	2.0 (0.5)

23. Secondary Outcome Measure:

Measure Title	Percent Change From Baseline in Beta 2 Microglobulin Levels During the Double-Blind Treatment Period
Measure Description	Beta 2 Microglobulin is a biological marker of inflammation. If baseline value was equal to 0, it was replaced by 0.1 to calculate the change from baseline.
Time Frame	Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	38	44
Percent Change From Baseline in Beta 2 Microglobulin Levels During the Double-Blind Treatment Period [units: percent change] Mean (Standard Deviation)		
Week 1 (n=38,44)	2.2 (18.1)	4.2 (19.6)
Week 4 (n=37,44)	-2.3 (14.1)	-0.8 (19.4)

24. Secondary Outcome Measure:

Measure Title	Bone Mineral Density

Measure Description	To describe bone mineral density (BMD), standardized values were calculated for lumbar spine, hip, femoral neck, and trochanter, taking into account the type of Dual energy X ray absorptiometry (DXA) used. All DXA at baseline were taken into account (done from before screening to Week 8). DXA at end of study were taken into account if they were done after at least 6 infusions of tocilizumab. Values were measured in milligrams per square centimeter (mg/cm^2).
Time Frame	Baseline and Week 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilizumab
Number of Participants Analyzed	90
Bone Mineral Density [units: mg/cm^2] Mean (Standard Deviation)	
Lumbar spine, Baseline (n=89)	1018.0 (155.4)
Lumbar spine, Week 48 (n=82)	1033.4 (157.9)
Hip, Baseline (n=90)	887.3 (129.8)
Hip, Week 48 (n=83)	891.3 (131.6)
Femoral neck, Baseline (n=90)	825.0 (122.7)
Femoral neck, Week 48 (n=83)	821.8 (121.6)
Trochanter, Baseline (n=90)	696.2 (124.3)
Trochanter, Week 48 (n=83)	700.3 (122.7)

25. Secondary Outcome Measure:

Measure Title	Percentage of Participants Treated With Corticosteroids Over the 1-Year Tocilizumab Period
Measure Description	
Time Frame	Baseline, Weeks 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, and 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilizumab
Number of Participants Analyzed	103
Percentage of Participants Treated With Corticosteroids Over the 1-Year Tocilizumab Period [units: percentage of participants]	
Baseline (n=103)	74
Week 8 (n=99)	74
Week 12 (n=97)	71
Week 16 (n=95)	71
Week 20 (n=93)	70
Week 24 (n=93)	71
Week 28 (n=91)	68
Week 32 (n=90)	68
Week 36 (n=85)	69
Week 40 (n=82)	65
Week 44 (n=82)	60

	Placebo, Tocilizumab
Week 48 (n=82)	60

26. Secondary Outcome Measure:

Measure Title	S-Sclerostin and P-Dkk1 (Wnt Signaling Inhibitor Dickkopf) Over the 1-Year Tocilizumab Period
Measure Description	S-Sclerostin and P-Dkk1 are biological markers of bone and cartilage metabolism measured as picograms/milliliter (pg/mL). Baseline is the closest value plus or minus (+/-) 1 month around the first tocilizumab infusion. If values before and after the first infusion were eligible, the value before was taken into account.
Time Frame	Baseline, Weeks 12, 24, and 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilizumab
Number of Participants Analyzed	103
S-Sclerostin and P-Dkk1 (Wnt Signaling Inhibitor Dickkopf) Over the 1-Year Tocilizumab Period [units: pg/mL] Mean (Standard Deviation)	
S-Sclerostin, Baseline (n=103)	0.51 (0.22)
S-Sclerostin, Week 12 (n=93)	0.55 (0.20)
S-Sclerostin, Week 24 (n=84)	0.51 (0.19)
S-Sclerostin, Week 48 (n=75)	0.54 (0.21)
P-Dkk1, Baseline (n=102)	847.50 (610.22)

	Placebo, Tocilizumab
P-Dkk1, Week 12 (n=86)	572.45 (350.85)
P-Dkk1, Week 48 (n=72)	685.79 (482.73)

27. Secondary Outcome Measure:

Measure Title	Serum Procollagen Type II N-Propeptide (s-PIINP), Serum Procollagen Type I N Propeptide (s-PINP), and Serum Carboxy-Terminal Collagen Crosslinks-1 (s-CTX-I) Over the 1-Year Tocilizumab Period
Measure Description	S-PIIINP, S-CTX-I, and S-PINP are biological markers of bone and cartilage metabolism. Baseline is the closest value +/- 1 month around the first tocilizumab infusion. If values before and after the first infusion were eligible, the value before was taken into account.
Time Frame	Baseline and Weeks 12, 24, and 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilzumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilzumab
Number of Participants Analyzed	103
Serum Procollagen Type II N-Propeptide (s-PIINP), Serum Procollagen Type I N Propeptide (s-PINP), and Serum Carboxy-Terminal Collagen Crosslinks-1 (s-CTX-I) Over the 1-Year Tocilizumab Period [units: ng/mL] Mean (Standard Deviation)	
s-PIIINP, Baseline (n=103)	5.59 (2.06)
s-PIIINP, Week 12 (n=94)	6.07 (2.39)

	Placebo, Tocilzumab
s-PIIINP, Week 24 (n=85)	5.74 (2.27)
s-PIIINP, Week 48 (n=77)	5.86 (2.12)
s-CTX-I, Baseline (n=103)	0.35 (0.22)
s-CTX-I, Week 12 (n=93)	0.35 (0.20)
s-CTX-I, Week 48 (n=77)	0.33 (0.18)
s-PINP, Baseline (n=103)	41.15 (23.95)
s-PINP, Week 12 (n=93)	52.33 (32.66)
s-PINP, Week 48 (n=77)	53.16 (30.14)

28. Secondary Outcome Measure:

Measure Title	Serum Osteogenic Growth Peptide (s-OGP) Over the 1-Year Tocilizumab Period
Measure Description	S-OGP is a biological marker of bone and cartilage metabolism measured as picomoles per liter (pmol/L). Baseline is the closest value +/- 1 month around the first tocilizumab infusion. If values before and after the first infusion were eligible, the value before was taken into account.
Time Frame	Baseline and Weeks 12 and 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilzumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilzumab
Number of Participants Analyzed	103

	Placebo, Tocilzumab
Serum Osteogenic Growth Peptide (s-OGP) Over the 1-Year Tocilizumab Period [units: pmol/L] Mean (Standard Deviation)	
Baseline (n=103)	3.97 (1.27)
Week 12 (n=93)	3.94 (1.20)
Week 48 (n=77)	3.90 (1.21)

29. Secondary Outcome Measure:

Measure Title	Weekly Methotrexate (MTX) Dose
Measure Description	Before entering the study, participants had to be treated with MTX for at least 12 weeks and at a stable dose for at least 8 weeks before the screening visit (10-25 mg per week [mg/week] of oral or parenteral MTX). During the study, treatment with MTX had to be stable during the first month and then could be continued or modified, at the investigator's discretion.
Time Frame	Baseline and Weeks 24 and 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilzumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilzumab
Number of Participants Analyzed	103
Weekly Methotrexate (MTX) Dose [units: mg/week] Mean (Standard Deviation)	

	Placebo, Tocilzumab
Baseline (n=103)	17.7 (4.2)
Week 24 (n=91)	17.1 (4.4)
Week 48 (n=77)	16.9 (4.6)

30. Secondary Outcome Measure:

Measure Title	HAQ-DI During the Double-Blind Treatment Period
Measure Description	HAQ-DI: participant-reported assessment of ability to perform tasks in 8 categories of daily living activities: dress/ groom; arise; eat; walk; reach; grip; hygiene; and common activities over past week. Each item scored on 4-point scale from 0 to 3: 0=no difficulty; 1=some difficulty; 2=much difficulty; 3=unable to do. Overall score was computed as the sum of domain scores and divided by the number of domains answered. Total possible score range 0-3 where 0 = least difficulty and 3 = extreme difficulty.
Time Frame	Screening and Week 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
HAQ-DI During the Double-Blind Treatment Period [units: units on a scale] Mean (Standard Deviation)		
Screening (n=50,53)	1.62 (0.56)	1.60 (0.58)

	Placebo, Tocilizumab	Tocilizumab
Week 4 (n=50,51)	1.44 (0.60)	1.39 (0.65)
Change at Week 4 (n=50,51)	-0.18 (0.47)	-0.22 (0.49)

31. Secondary Outcome Measure:

Measure Title	HAQ-DI During the Open Treatment Period
Measure Description	HAQ-DI: participant-reported assessment of ability to perform tasks in 8 categories of daily living activities: dress/ groom; arise; eat; walk; reach; grip; hygiene; and common activities over past week. Each item scored on 4-point scale from 0 to 3: 0=no difficulty; 1=some difficulty; 2=much difficulty; 3=unable to do. Overall score was computed as the sum of domain scores and divided by the number of domains answered. Total possible score range 0-3 where 0 = least difficulty and 3 = extreme difficulty.
Time Frame	Baseline and Weeks 12, 24, 36, and 48
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	47	56
HAQ-DI During the Open Treatment Period [units: units on a scale] Mean (Standard Deviation)		
Baseline (n=47,56)	1.45 (0.61)	1.62 (0.57)
Week 12 (n=45,49)	1.19 (0.68)	1.06 (0.70)

	Placebo, Tocilizumab	Tocilizumab
Change at Week 12 (n=45,49)	-0.29 (0.52)	-0.62 (0.62)
Week 24 (n=39,50)	1.00 (0.69)	1.01 (0.71)
Change at Week 24 (n=39,50)	-0.50 (0.54)	-0.68 (0.61)
Week 36 (n=39,45)	1.05 (0.76)	1.02 (0.71)
Change at Week 36 (n=39,45)	-0.44 (0.75)	-0.64 (0.64)
Week 48 (n=37,45)	0.98 (0.78)	0.95 (0.63)
Change at Week 48 (n=37,45)	-0.47 (0.71)	-0.72 (0.60)

32. Secondary Outcome Measure:

Measure Title	Functional Assessment of Chronic Illness in Therapy - Fatigue (FACIT-F) During the Double-Blind Treatment Period
Measure Description	FACIT-F is a 13-item questionnaire. Participants scored each item on a 5-point scale: 0 (Not at all) to 4 (Very much). The larger the participant's response to the questions (with the exception of 2 negatively stated), the greater the patient's fatigue. For all questions, except for the 2 negatively stated ones, the code was reversed and a new score was calculated as (4 minus the participant's response). The sum of all responses resulted in the FACIT-F score for a total possible score of 0 (worse score) to 52 (better score). A higher score reflects an improvement in the participant's health status. Baseline = Last available value before Day 0 (screening or Day 0) for participants with first tocilizumab infusion at Day 0 and last value available before Week 4 (Week 1 or Week 4) for participants with first tocilizumab infusion at Week 4.
Time Frame	Day 0, Week 1, and Week 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
Functional Assessment of Chronic Illness in Therapy - Fatigue (FACIT-F) During the Double-Blind Treatment Period [units: units on a scale] Mean (Standard Deviation)		
Day 0 (n=50,52)	23.9 (10.1)	26.0 (10.6)
Week 1 (n=48,52)	27.3 (11.7)	27.7 (10.4)
Week 4 (n=49,52)	29.2 (11.0)	28.9 (11.0)

33. Secondary Outcome Measure:

Measure Title	Percent Change From Baseline in FACIT-F During the Double-Blind Treatment Period
Measure Description	FACIT-F is a 13-item questionnaire. Participants scored each item on a 5-point scale: 0 (Not at all) to 4 (Very much). The larger the participant's response to the questions (with the exception of 2 negatively stated), the greater the patient's fatigue. For all questions, except for the 2 negatively stated ones, the code was reversed and a new score was calculated as (4 minus the participant's response). The sum of all responses resulted in the FACIT-F score for a total possible score of 0 (worse score) to 52 (better score). A higher score reflects an improvement in the participant's health status. Baseline = Last available value before Day 0 (screening or Day 0) for participants with first tocilizumab infusion at Day 0 and last value available before Week 4 (Week 1 or Week 4) for participants with first tocilizumab infusion at Week 4.
Time Frame	Week 1 and Week 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	49	52
Percent Change From Baseline in FACIT-F During the Double-Blind Treatment Period [units: percent change] Mean (Standard Deviation)		
Week 1 (n=48,51)	24.6 (29.0)	22.7 (61.5)
Week 4 (n=49,52)	37.7 (77.1)	41.7 (167.9)

34. Secondary Outcome Measure:

Measure Title	FACIT-F During the Open Treatment Period
Measure Description	FACIT-F is a 13-item questionnaire. Participants scored each item on a 5-point scale: 0 (Not at all) to 4 (Very much). The larger the participant's response to the questions (with the exception of 2 negatively stated), the greater the patient's fatigue. For all questions, except for the 2 negatively stated ones, the code was reversed and a new score was calculated as (4 minus the participant's response). The sum of all responses resulted in the FACIT-F score for a total possible score of 0 (worse score) to 52 (better score). A higher score reflects an improvement in the participant's health status. Baseline = Last available value before Day 0 (screening or Day 0) for participants with first tocilizumab infusion at Day 0 and last value available before Week 4 (Week 1 or Week 4) for participants with first tocilizumab infusion at Week 4.
Time Frame	Baseline, Weeks 12, 24, 36, and 48
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilzumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilzumab
Number of Participants Analyzed	102
FACIT-F During the Open Treatment Period [units: units on a scale] Mean (Standard Deviation)	
Baseline (n=102)	27.1 (11.1)
Week 12 (n=93)	33.7 (11.2)
Week 24 (n=90)	35.4 (10.4)
Week 36 (n=82)	34.0 (10.3)
Week 48 (n=82)	34.9 (10.6)

35. Secondary Outcome Measure:

Measure Title	Hemoglobin Concentration During the Double-Blind Treatment Period
Measure Description	Hemoglobin concentrations were determined at each visit to evaluate anemia in participants and measured as grams per deciliter (g/dL).
Time Frame	Baseline and Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53

	Placebo, Tocilizumab	Tocilizumab
Hemoglobin Concentration During the Double-Blind Treatment Period [units: g/dL] Mean (Standard Deviation)		
Baseline (n=50,53)	12.97 (1.37)	12.74 (1.49)
Week 1 (n=50,51)	12.96 (1.33)	13.04 (1.38)
Change at Week 1 (n=50,51)	-0.01 (0.54)	0.34 (0.54)
Week 4 (n=50,53)	12.88 (1.46)	13.10 (1.41)
Change at Week 4 (n=50,53)	-0.09 (0.54)	0.36 (0.69)

36. Secondary Outcome Measure:

Measure Title	Hemoglobin Concentration During the Open Treatment Period
Measure Description	Hemoglobin concentrations were determined at each visit to evaluate anemia in participants and measured as g/dL.
Time Frame	Baseline, Weeks 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, and 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilzumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilzumab
Number of Participants Analyzed	103
Hemoglobin Concentration During the Open Treatment Period [units: g/dL] Mean (Standard Deviation)	

	Placebo, Tocilzumab
Baseline (n=103)	12.80 (1.47)
Week 8 (n=99)	13.14 (1.41)
Week 12 (n=97)	13.37 (1.40)
Week 16 (n=95)	13.24 (1.51)
Week 20 (n=91)	13.27 (1.46)
Week 24 (n=92)	13.38 (1.43)
Week 28 (n=91)	13.47 (1.32)
Week 32 (n=90)	13.46 (1.35)
Week 36 (n=84)	13.50 (1.31)
Week 40 (n=81)	13.49 (1.35)
Week 44 (n=82)	13.48 (1.37)
Week 48 (n=81)	13.64 (1.32)

37. Secondary Outcome Measure:

Measure Title	Tender Joint Count (TJC) Based on 28-Joint Count During the Double-Blind Treatment Period
Measure Description	Twenty-eight joints were assessed for tenderness. Joints were classified as tender (1)/not tender (0) giving a total possible TJC score of 0 to 28. Baseline = value at Day 0 if available, value at screening otherwise.
Time Frame	Baseline and Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

	Description
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
Tender Joint Count (TJC) Based on 28-Joint Count During the Double-Blind Treatment Period [units: tender joints] Mean (Standard Deviation)		
Baseline (n=50,53)	12.0 (6.6)	13.4 (6.7)
Week 1 (n=49,53)	11.0 (7.1)	10.6 (6.7)
Week 4 (n=50,53)	10.6 (6.7)	9.9 (7.7)

38. Secondary Outcome Measure:

Measure Title	Percent Change From Baseline in TJC Based on 28-Joint Count During the Double-Blind Treatment Period
Measure Description	Twenty-eight joints were assessed for tenderness. Joints were classified as tender (1)/not tender (0) giving a total possible TJC score of 0 to 28.
Time Frame	Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
Percent Change From Baseline in TJC Based on 28-Joint Count During the Double-Blind Treatment Period [units: percent change] Mean (Standard Deviation)		
Week 1 (n=49,53)	3.4 (74.4)	16.7 (266.7)
Week 4 (n=50,53)	25.7 (180.4)	9.3 (268.6)

39. Secondary Outcome Measure:

Measure Title	TJC Based on 28-Joint Count During the Open Treatment Period
Measure Description	Twenty-eight joints were assessed for tenderness and joints were classified as tender (1)/not tender (0), giving a total possible tender joint count score of 0 to 28. Baseline = Last value available before Day 0 (selection or Day 0) for placebo and last value available before Week 4 (Week 1 or Week 4) for tocilizumab group.
Time Frame	Baseline and Weeks 12, 24, 36, and 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilizumab
Number of Participants Analyzed	103
TJC Based on 28-Joint Count During the Open Treatment Period [units: tender joints] Mean (Standard Deviation)	

	Placebo, Tocilizumab
Baseline (n=103)	12.3 (6.9)
Week 12 (n=97)	5.5 (5.6)
Week 24 (n=92)	4.0 (4.7)
Week 36 (n=84)	3.6 (4.5)
Week 48 (n=82)	3.3 (4.7)

40. Secondary Outcome Measure:

Measure Title	TJC Based on 40-Joint Count During the Double-Blind Treatment Period
Measure Description	Forty joints were assessed for tenderness (5 MCP [left and right] joints, 5 PIP [left and right joints], left and right wrists, elbows, shoulders, knees, and ankles, and 5 MTP [left and right] joints). Joints were classified as tender (1)/not tender (0) giving a total possible TJC score of 0 to 40. Baseline = value at Day 0 if available, value at screening otherwise.
Time Frame	Baseline and Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
TJC Based on 40-Joint Count During the Double-Blind Treatment Period [units: tender joints]		

	Placebo, Tocilizumab	Tocilizumab
Mean (Standard Deviation)		
Baseline (n=50,53)	17.7 (9.1)	18.3 (8.0)
Week 1 (n=49,53)	16.3 (9.9)	14.6 (9.4)
Week 4 (n=50,53)	15.0 (8.6)	14.0 (10.7)

41. Secondary Outcome Measure:

Measure Title	Percent Change From Baseline in TJC Based on 40-Joint Count During the Double-Blind Treatment Period
Measure Description	Forty joints were assessed for tenderness (5 MCP [left and right] joints, 5 PIP [left and right joints], left and right wrists, elbows, shoulders, knees, and ankles, and 5 MTP [left and right] joints). Joints were classified as tender (1)/not tender (0) giving a total possible TJC score of 0 to 40.
Time Frame	Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
Percent Change From Baseline in TJC Based on 40-Joint Count During the Double-Blind Treatment Period [units: percent change] Mean (Standard Deviation)		
Week 1 (n=49,53)	-2.6 (59.5)	-22.1 (39.6)

	Placebo, Tocilizumab	Tocilizumab
Week 4 (n=50,53)	-1.5 (63.5)	-23.1 (49.3)

42. Secondary Outcome Measure:

Measure Title	TJC Based on 40-Joint Count During the Open Treatment Period
Measure Description	Forty joints were assessed for tenderness (5 MCP [left and right] joints, 5 PIP [left and right joints], left and right wrists, elbows, shoulders, knees, and ankles, and 5 MTP [left and right] joints). Joints were classified as tender (1)/not tender (0) giving a total possible TJC score of 0 to 40. Baseline = Last value available before Day 0 (selection or Day 0) for placebo and last value available before Week 4 (Week 1 or Week 4) for tocilizumab group.
Time Frame	Baseline and Weeks 12, 24, 36, and 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilizumab
Number of Participants Analyzed	103
TJC Based on 40-Joint Count During the Open Treatment Period [units: tender joints] Mean (Standard Deviation)	
Baseline (n=103)	17.0 (8.7)
Week 12 (n=97)	7.9 (7.7)
Week 24 (n=92)	5.9 (6.5)
Week 36 (n=84)	5.2 (6.2)

	Placebo, Tocilizumab
Week 48 (n=82)	5.0 (6.5)

43. Secondary Outcome Measure:

Measure Title	Swollen Joint Count (SJC) Based on 28-Joint Count During the Double-Blind Treatment Period
Measure Description	Twenty-eight joints were assessed for swelling. Joints were classified as swollen (1)/not swollen (0) giving a total possible SJC score of 0 to 28. Baseline = value at Day 0 if available, value at screening otherwise.
Time Frame	Baseline and Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
Swollen Joint Count (SJC) Based on 28-Joint Count During the Double-Blind Treatment Period [units: swollen joints] Mean (Standard Deviation)		
Baseline (n=50,53)	8.3 (4.2)	8.5 (4.5)
Week 1 (n=49,53)	6.9 (4.4)	7.0 (4.8)
Week 4 (n=50,53)	7.7 (4.6)	5.8 (3.8)

44. Secondary Outcome Measure:

Measure Title	Percent Change From Baseline in SJC Based on 28-Joint Count During the Double-Blind Treatment Period
Measure Description	Twenty-eight joints were assessed for swelling. Joints were classified as swollen (1)/not swollen (0) giving a total possible SJC score of 0 to 28.
Time Frame	Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
Percent Change From Baseline in SJC Based on 28-Joint Count During the Double-Blind Treatment Period [units: percent change] Mean (Standard Deviation)		
Week 1 (n=49,53)	-12.0 (54.0)	-10.9 (70.6)
Week 4 (n=50,53)	-1.1 (53.7)	-27.3 (47.6)

45. Secondary Outcome Measure:

Measure Title	Swollen Joint Count (SJC) Based on 28-Joint Count During the Open Treatment Period

Measure Description	Twenty-eight joints were assessed for swelling (5 MCP [left and right] joints, 5 PIP [left and right joints], left and right wrists, elbows, shoulders, knees, and ankles, and 5 MTP [left and right] joints) . Joints were classified as swollen (1)/not swollen (0) giving a total possible SJC score of 0 to 28. Baseline = Last value available before Day 0 (selection or Day 0) for placebo and last value available before Week 4 (Week 1 or Week 4) for tocilizumab group.
Time Frame	Baseline and Weeks 12, 24, 36, and 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilizumab
Number of Participants Analyzed	103
Swollen Joint Count (SJC) Based on 28-Joint Count During the Open Treatment Period [units: swollen joints] Mean (Standard Deviation)	
Baseline (n=103)	8.2 (4.6)
Week 12 (n=97)	3.8 (4.0)
Week 24 (n=92)	3.1 (3.4)
Week 36 (n=84)	2.2 (3.0)
Week 48 (n=82)	1.7 (2.6)

46. Secondary Outcome Measure:

Measure Title	SJC Based on 40-Joint Count During the Double-Blind Treatment Period

Measure Description	Forty joints were assessed for swelling (5 MCP [left and right] joints, 5 PIP [left and right joints], left and right wrists, elbows, shoulders, knees, and ankles, and 5 MTP [left and right] joints). Joints were classified as swollen (1)/not swollen (0) giving a total possible SJC score of 0 to 40. Baseline = value at Day 0 if available, value at screening otherwise.
Time Frame	Baseline and Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
SJC Based on 40-Joint Count During the Double-Blind Treatment Period [units: swollen joints] Mean (Standard Deviation)		
Baseline (n=50,53)	10.1 (5.0)	10.4 (5.1)
Week 1 (n=49,53)	8.7 (5.3)	8.0 (5.3)
Week 4 (n=50,53)	9.8 (6.0)	6.7 (4.5)

47. Secondary Outcome Measure:

Measure Title	Percent Change From Baseline in SJC Based on 40-Joint Count During the Double-Blind Treatment Period
Measure Description	Forty joints were assessed for swelling (5 MCP [left and right] joints, 5 PIP [left and right joints], left and right wrists, elbows, shoulders, knees, and ankles, and 5 MTP [left and right] joints). Joints were classified as swollen (1)/not swollen (0) giving a total possible SJC score of 0 to 40.

Time Frame	Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
Percent Change From Baseline in SJC Based on 40-Joint Count During the Double-Blind Treatment Period [units: percent change] Mean (Standard Deviation)		
Week 1 (n=49,53)	-9.2 (58.1)	-19.2 (45.3)
Week 4 (n=50,53)	7.7 (73.8)	-30.0 (45.9)

48. Secondary Outcome Measure:

Measure Title	SJC Based on 40-Joint Count During the Open Treatment Period
Measure Description	Forty joints were assessed for swelling (5 MCP [left and right] joints, 5 PIP [left and right joints], left and right wrists, elbows, shoulders, knees, and ankles, and 5 MTP [left and right] joints). Joints were classified as swollen (1)/not swollen (0) for a total possible score of 0 to 40. Baseline = Last value available before Day 0 (selection or Day 0) for placebo and last value available before Week 4 (Week 1 or Week 4) for tocilizumab group.
Time Frame	Baseline and Weeks 12, 24, 36, and 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilizumab
Number of Participants Analyzed	103
SJC Based on 40-Joint Count During the Open Treatment Period [units: swollen joints] Mean (Standard Deviation)	
Baseline (n=103)	10.2 (5.7)
Week 12 (n=97)	4.4 (4.7)
Week 24 (n=92)	3.5 (3.7)
Week 36 (n=84)	2.5 (3.3)
Week 48 (n=82)	2.1 (3.0)

49. Secondary Outcome Measure:

Measure Title	Disease Activity Score Based on 28-Joints Count (DAS28) During the Double-Blind Treatment Period
Measure Description	DAS28 calculated from the number of swollen joints and tender joints using the 28-joint count, the erythrocyte sedimentation rate and global health assessment (participant-rated global assessment of disease activity using 10-mm VAS); DAS28 score ranged from 0 to 10, where higher scores correspond to greater disease activity. DAS28 less than or equal to (≤3.2) = low disease activity, DAS28 greater than (>)3.2 to 5.1 = moderate to high disease activity.
Time Frame	Baseline and Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
Disease Activity Score Based on 28-Joints Count (DAS28) During the Double-Blind Treatment Period [units: units on a scale] Mean (Standard Deviation)		
Baseline (n=50,53)	5.66 (1.02)	5.64 (1.04)
Week 1 (n=41,40)	5.40 (1.04)	4.41 (1.05)
Change at Week 1 (n=41,40)	-0.43 (0.81)	-1.12 (0.61)
Week 4 (n=45,50)	5.27 (1.00)	4.00 (1.26)
Change at Week 4 (n=45,50)	-0.43 (0.90)	-1.68 (0.94)

50. Secondary Outcome Measure:

Measure Title	DAS28 During the Open Treatment Period
Measure Description	DAS28 calculated from the number of swollen joints and tender joints using the 28-joint count, the erythrocyte sedimentation rate and global health assessment (participant-rated global assessment of disease activity using 10-mm VAS); DAS28 score ranged from 0 to 10, where higher scores correspond to greater disease activity. DAS28 less than or equal to (≤3.2) = low disease activity, DAS28 greater than (>)3.2 to 5.1 = moderate to high disease activity.
Time Frame	Baseline and Weeks 12, 24, 36, and 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilizumab
Number of Participants Analyzed	103
DAS28 During the Open Treatment Period [units: units on a scale] Mean (Standard Deviation)	
Baseline (n=102)	5.51 (1.04)
Week 12 (n=95)	2.98 (1.40)
Week 24 (n=89)	2.64 (1.31)
Week 36 (n=83)	2.51 (1.36)
Week 48 (n=79)	2.22 (1.28)

51. Secondary Outcome Measure:

Measure Title	Disease Activity Score Based on 40-Joints Count (DAS40) During the Double-Blind Treatment Period
Measure Description	DAS40 calculated from the number of swollen joints and tender joints using the 40-joint count, the erythrocyte sedimentation rate and global health assessment (participant-rated global assessment of disease activity using 10-mm VAS); DAS28 score ranged from 0 to 10, where higher scores correspond to greater disease activity.
Time Frame	Baseline and Weeks 1 and 4
Safety Issue?	No

Analysis Population Description

ITT Population; n=number of participants assessed for the specified parameter at a given visit. Changes from baseline were described for participants without missing data.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.

Measured Values

	Placebo, Tocilizumab	Tocilizumab
Number of Participants Analyzed	50	53
Disease Activity Score Based on 40-Joints Count (DAS40) During the Double-Blind Treatment Period [units: units on a scale] Mean (Standard Deviation)		
Baseline (n=50,53)	6.15 (1.03)	6.08 (1.04)
Week 1 (n=41,40)	5.88 (1.12)	4.71 (1.16)
Change at Week 1 (n=41,40)	-0.43 (0.85)	-1.25 (0.64)
Week 4 (n=45,50)	5.70 (1.03)	4.39 (1.37)
Change at Week 4 (n=45,50)	-0.49 (1.03)	-1.75 (1.03)

52. Secondary Outcome Measure:

Measure Title	DAS40 During the Open Treatment Period
Measure Description	DAS40 was calculated from the number of swollen joints and tender joints using the 40-joint count, the erythrocyte sedimentation rate, and global health assessment (participant-rated global assessment of disease activity using 10-mm VAS); DAS40 score ranged from 0 to 10, where higher scores correspond to greater disease activity.
Time Frame	Baseline and Weeks 12, 24, 36, and 48
Safety Issue?	No

Analysis Population Description

One-Year Efficacy Population; n=number of participants assessed for the specified parameter at a given visit.

Reporting Groups

	Description
Placebo, Tocilizumab	Participants received either tocilizumab 8 mg/kg (800 mg maximum) IV or placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4 (Open Treatment Period), all participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Measured Values

	Placebo, Tocilizumab
Number of Participants Analyzed	102
DAS40 During the Open Treatment Period [units: units on a scale] Mean (Standard Deviation)	
Baseline (n=102)	5.96 (1.06)
Week 12 (n=95)	3.27 (1.49)
Week 24 (n=89)	2.89 (1.40)
Week 36 (n=83)	2.76 (1.42)
Week 48 (n=79)	2.48 (1.40)

Reported Adverse Events

Time Frame	Adverse events were recorded throughout the study, from date of Screening until the end of study at Week 48.
Additional Description	[Not specified]

Reporting Groups

	Description
Tocilizumab	Participants received tocilizumab 8 mg/kg (800 mg maximum) IV once every 4 weeks up to 12 months (up to Week 44), for a maximum of 12 infusions.
Placebo, Tocilizumab	Participants received placebo solution (containing polysorbate 80, sucrose, and water for injection) IV during the Double-Blind Treatment Period on Day 0. Starting at Week 4, participants received tocilizumab 8 mg/kg (800 mg maximum) IV, once every 4 weeks up to 11 months (up to Week 44), for a maximum of 11 infusions.

Serious Adverse Events

	Tocilizumab	Placebo, Tocilizumab
	Affected/At Risk (%)	Affected/At Risk (%)
Total	13/53 (24.53%)	11/50 (22%)
Blood and lymphatic system disorders		
Anaemia [A] *	1/53 (1.89%)	0/50 (0%)
Cardiac disorders		
Myocardial infarction [A] *	0/53 (0%)	1/50 (2%)
General disorders		
Malaise [A] *	0/53 (0%)	1/50 (2%)
Pyrexia [A] *	1/53 (1.89%)	0/50 (0%)
Infections and infestations		
Bronchitis [A] *	0/53 (0%)	1/50 (2%)
Pneumonia [A] *	0/53 (0%)	1/50 (2%)
Pyelonephritis [A] *	2/53 (3.77%)	0/50 (0%)
Sepsis [A] *	0/53 (0%)	1/50 (2%)
Injury, poisoning and procedural complications		
Chest injury [A] *	0/53 (0%)	1/50 (2%)
Rib fracture [A] *	0/53 (0%)	1/50 (2%)
Investigations		
ALT increased [A] *	1/53 (1.89%)	0/50 (0%)
Transaminases increased [A] *	0/53 (0%)	1/50 (2%)
Metabolism and nutrition disorders		
Diabetes mellitus inadequate control [A] *	1/53 (1.89%)	0/50 (0%)
Musculoskeletal and connective tissue disorders		
Arthralgia [A] *	1/53 (1.89%)	0/50 (0%)

	Tocilizumab	Placebo, Tocilizumab
	Affected/At Risk (%)	Affected/At Risk (%)
Chondrolysis [A] *	0/53 (0%)	1/50 (2%)
Musculoskeletal pain [A] *	1/53 (1.89%)	0/50 (0%)
Osteoarthritis [A] *	0/53 (0%)	1/50 (2%)
Plantar fasciitis [A] *	1/53 (1.89%)	0/50 (0%)
Rheumatoid nodule [A] *	1/53 (1.89%)	0/50 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Ameloblastoma [A] *	1/53 (1.89%)	0/50 (0%)
Nervous system disorders		
Coma [A] *	1/53 (1.89%)	0/50 (0%)
Sciatica [A] *	1/53 (1.89%)	0/50 (0%)
Pregnancy, puerperium and perinatal conditions		
Abortion spontaneous [A] *	1/53 (1.89%)	0/50 (0%)
Respiratory, thoracic and mediastinal disorders		
Dyspnoea [A] *	0/53 (0%)	1/50 (2%)
Lung disorder [A] *	0/53 (0%)	1/50 (2%)
Pulmonary embolism [A] *	1/53 (1.89%)	0/50 (0%)
Skin and subcutaneous tissue disorders		
Dermatitis allergic [A] *	0/53 (0%)	1/50 (2%)
Vascular disorders		
Deep vein thrombosis [A] *	1/53 (1.89%)	0/50 (0%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Tocilizumab	Placebo, Tocilizumab
	Affected/At Risk (%)	Affected/At Risk (%)
Total	30/53 (56.6%)	15/50 (30%)
Blood and lymphatic system disorders		
Anaemia [A] *	1/53 (1.89%)	1/50 (2%)
Eosinophilia [A] *	1/53 (1.89%)	0/50 (0%)
Hypochromic anaemia [A] *	1/53 (1.89%)	1/50 (2%)
Lymphadenopathy [A] *	1/53 (1.89%)	0/50 (0%)
Lymphopenia [A] *	1/53 (1.89%)	0/50 (0%)
Microcytic anaemia [A] *	1/53 (1.89%)	0/50 (0%)
Neutropenia [A] *	5/53 (9.43%)	6/50 (12%)
Polycythaemia [A] *	0/53 (0%)	1/50 (2%)
Thrombocytopenia [A] *	1/53 (1.89%)	3/50 (6%)
Cardiac disorders		
Bradycardia [A] *	0/53 (0%)	1/50 (2%)
Extrasystoles [A] *	1/53 (1.89%)	0/50 (0%)
Palpitations [A] *	1/53 (1.89%)	0/50 (0%)
Tachycardia [A] *	1/53 (1.89%)	0/50 (0%)
Congenital, familial and genetic disorders		
Thalassaemia beta [A] *	0/53 (0%)	1/50 (2%)
Ear and labyrinth disorders		
Auricular pseudocyst [A] *	0/53 (0%)	1/50 (2%)
Ear pain [A] *	1/53 (1.89%)	1/50 (2%)
Tinnitus [A] *	0/53 (0%)	1/50 (2%)

	Tocilizumab	Placebo, Tocilizumab
	Affected/At Risk (%)	Affected/At Risk (%)
Vertigo [A] *	4/53 (7.55%)	0/50 (0%)
Eye disorders		
Chalazion [A] *	1/53 (1.89%)	0/50 (0%)
Conjunctivitis [A] *	2/53 (3.77%)	0/50 (0%)
Eyelid cyst [A] *	0/53 (0%)	2/50 (4%)
Ocular discomfort [A] *	0/53 (0%)	1/50 (2%)
Visual impairment [A] *	0/53 (0%)	1/50 (2%)
Xerophthalmia [A] *	0/53 (0%)	1/50 (2%)
Gastrointestinal disorders		
Abdominal pain [A] *	1/53 (1.89%)	1/50 (2%)
Abdominal pain upper [A] *	2/53 (3.77%)	4/50 (8%)
Aerophagia [A] *	1/53 (1.89%)	0/50 (0%)
Aphthous stomatitis [A] *	5/53 (9.43%)	2/50 (4%)
Constipation [A] *	3/53 (5.66%)	3/50 (6%)
Diarrhoea [A] *	8/53 (15.09%)	3/50 (6%)
Diverticulum intestinal [A] *	1/53 (1.89%)	0/50 (0%)
Dyspepsia [A] *	1/53 (1.89%)	0/50 (0%)
Flatulence [A] *	1/53 (1.89%)	0/50 (0%)
Gastric polyps [A] *	1/53 (1.89%)	0/50 (0%)
Gastritis [A] *	1/53 (1.89%)	1/50 (2%)
Gingival recession [A] *	1/53 (1.89%)	1/50 (2%)
Gingivitis [A] *	0/53 (0%)	1/50 (2%)

	Tocilizumab	Placebo, Tocilizumab
	Affected/At Risk (%)	Affected/At Risk (%)
Haemorrhoids [A] *	0/53 (0%)	1/50 (2%)
Nausea [A] *	3/53 (5.66%)	3/50 (6%)
Salivary hypersecretion [A] *	0/53 (0%)	1/50 (2%)
Sigmoiditis [A] *	0/53 (0%)	1/50 (2%)
Tongue ulceration [A] *	0/53 (0%)	1/50 (2%)
Tooth discolouration [A] *	0/53 (0%)	1/50 (2%)
Toothache [A] *	1/53 (1.89%)	1/50 (2%)
Vomiting [A] *	4/53 (7.55%)	0/50 (0%)
General disorders		
Asthenia [A] *	6/53 (11.32%)	3/50 (6%)
Chest discomfort [A] *	1/53 (1.89%)	1/50 (2%)
Chest pain [A] *	0/53 (0%)	1/50 (2%)
Extravasation [A] *	1/53 (1.89%)	0/50 (0%)
Fatigue [A] *	2/53 (3.77%)	3/50 (6%)
Malaise [A] *	0/53 (0%)	1/50 (2%)
Non-cardiac chest pain [A] *	1/53 (1.89%)	0/50 (0%)
Oedema peripheral [A] *	1/53 (1.89%)	1/50 (2%)
Pain [A] *	0/53 (0%)	1/50 (2%)
Pyrexia [A] *	2/53 (3.77%)	3/50 (6%)
Site of oppression [A] *	1/53 (1.89%)	0/50 (0%)
Vaccination site haematoma [A] *	0/53 (0%)	1/50 (2%)
Hepatobiliary disorders		

	Tocilizumab	Placebo, Tocilizumab
	Affected/At Risk (%)	Affected/At Risk (%)
Biliary cyst [A] *	1/53 (1.89%)	0/50 (0%)
Cholestasis [A] *	1/53 (1.89%)	0/50 (0%)
Cytolytic hepatitis [A] *	0/53 (0%)	4/50 (8%)
Hepatomegaly [A] *	0/53 (0%)	1/50 (2%)
Immune system disorders		
Hypersensitivity [A] *	0/53 (0%)	1/50 (2%)
Infections and infestations		
Bacterial infection [A] *	0/53 (0%)	1/50 (2%)
Bronchiolitis [A] *	0/53 (0%)	1/50 (2%)
Bronchitis [A] *	7/53 (13.21%)	8/50 (16%)
Bursitis infective [A] *	1/53 (1.89%)	0/50 (0%)
Chronic sinusitis [A] *	0/53 (0%)	1/50 (2%)
Cystitis [A] *	1/53 (1.89%)	0/50 (0%)
Dermo-hypodermitis [A] *	1/53 (1.89%)	0/50 (0%)
Ear infection [A] *	1/53 (1.89%)	0/50 (0%)
Escherichia urinary tract infection [A] *	2/53 (3.77%)	0/50 (0%)
Folliculitis [A] *	1/53 (1.89%)	1/50 (2%)
Fungal infection [A] *	1/53 (1.89%)	0/50 (0%)
Gastroenteritis [A] *	9/53 (16.98%)	4/50 (8%)
Herpes simplex [A] *	1/53 (1.89%)	1/50 (2%)
Herpes virus infection [A] *	1/53 (1.89%)	0/50 (0%)
Herpes zoster [A] *	1/53 (1.89%)	2/50 (4%)

	Tocilizumab	Placebo, Tocilizumab
	Affected/At Risk (%)	Affected/At Risk (%)
Herpes zoster ophthalmic [A] *	0/53 (0%)	1/50 (2%)
Infected bites [A] *	0/53 (0%)	1/50 (2%)
Influenza [A] *	3/53 (5.66%)	2/50 (4%)
Laryngitis [A] *	2/53 (3.77%)	0/50 (0%)
Localised infection [A] *	1/53 (1.89%)	0/50 (0%)
Lymphangitis [A] *	1/53 (1.89%)	0/50 (0%)
Mastoiditis [A] *	0/53 (0%)	1/50 (2%)
Nail bed infection [A] *	0/53 (0%)	1/50 (2%)
Nasopharyngitis [A] *	10/53 (18.87%)	7/50 (14%)
Oral fungal infection [A] *	1/53 (1.89%)	1/50 (2%)
Oral herpes [A] *	4/53 (7.55%)	1/50 (2%)
Pharyngitis [A] *	4/53 (7.55%)	1/50 (2%)
Pulpitis dental [A] *	1/53 (1.89%)	0/50 (0%)
Rhinitis [A] *	3/53 (5.66%)	2/50 (4%)
Sinusitis [A] *	2/53 (3.77%)	3/50 (6%)
Tinea pedis [A] *	0/53 (0%)	1/50 (2%)
Tonsillitis [A] *	4/53 (7.55%)	3/50 (6%)
Tooth abscess [A] *	0/53 (0%)	2/50 (4%)
Upper respiratory tract infection [A] *	0/53 (0%)	1/50 (2%)
Urinary tract infection [A] *	7/53 (13.21%)	3/50 (6%)
Vaginal infection [A] *	0/53 (0%)	1/50 (2%)
Vaginitis gardnerella [A] *	1/53 (1.89%)	0/50 (0%)

	Tocilizumab	Placebo, Tocilizumab
	Affected/At Risk (%)	Affected/At Risk (%)
Viral tonsillitis [A] *	1/53 (1.89%)	0/50 (0%)
Wound infection staphylococcal [A] *	0/53 (0%)	1/50 (2%)
Injury, poisoning and procedural complications		
Arthropod bite [A] *	0/53 (0%)	1/50 (2%)
Chillblains [A] *	0/53 (0%)	1/50 (2%)
Epicondylitis [A] *	0/53 (0%)	1/50 (2%)
Fall [A] *	1/53 (1.89%)	1/50 (2%)
Humerus fracture [A] *	1/53 (1.89%)	0/50 (0%)
Joint sprain [A] *	3/53 (5.66%)	0/50 (0%)
Limb injury [A] *	1/53 (1.89%)	2/50 (4%)
Tendon rupture [A] *	1/53 (1.89%)	0/50 (0%)
Tooth fracture [A] *	0/53 (0%)	1/50 (2%)
Traumatic haematoma [A] *	1/53 (1.89%)	0/50 (0%)
Investigations		
Alanine aminotransferase increased [A] *	4/53 (7.55%)	0/50 (0%)
Aspartate aminotransferase increased [A] *	1/53 (1.89%)	1/50 (2%)
C-reactive protein increased [A] *	2/53 (3.77%)	0/50 (0%)
Hepatic enzyme increased [A] *	0/53 (0%)	2/50 (4%)
Transaminases increased [A] *	2/53 (3.77%)	3/50 (6%)
Weight decreased [A] *	1/53 (1.89%)	0/50 (0%)
Weight increased [A] *	2/53 (3.77%)	1/50 (2%)
Metabolism and nutrition disorders		

	Tocilizumab	Placebo, Tocilizumab
	Affected/At Risk (%)	Affected/At Risk (%)
Decreased appetite [A] *	1/53 (1.89%)	0/50 (0%)
Dyslipidaemia [A] *	2/53 (3.77%)	6/50 (12%)
Hypercholesterolaemia [A] *	9/53 (16.98%)	0/50 (0%)
Hyperlipidaemia [A] *	1/53 (1.89%)	1/50 (2%)
Hypertriglyceridaemia [A] *	2/53 (3.77%)	1/50 (2%)
Musculoskeletal and connective tissue disorders		
Arthralgia [A] *	6/53 (11.32%)	3/50 (6%)
Arthritis [A] *	1/53 (1.89%)	0/50 (0%)
Back pain [A] *	3/53 (5.66%)	4/50 (8%)
Bone pain [A] *	0/53 (0%)	1/50 (2%)
Exostosis [A] *	0/53 (0%)	1/50 (2%)
Fibromyalgia [A] *	0/53 (0%)	1/50 (2%)
Foot deformity [A] *	0/53 (0%)	1/50 (2%)
Joint effusion [A] *	2/53 (3.77%)	0/50 (0%)
Muscle contracture [A] *	1/53 (1.89%)	0/50 (0%)
Muscle haemorrhage [A] *	2/53 (3.77%)	1/50 (2%)
Muscle spasms [A] *	2/53 (3.77%)	0/50 (0%)
Musculoskeletal chest pain [A] *	2/53 (3.77%)	0/50 (0%)
Musculoskeletal pain [A] *	0/53 (0%)	1/50 (2%)
Neck pain [A] *	2/53 (3.77%)	3/50 (6%)
Nodule on extremity [A] *	1/53 (1.89%)	0/50 (0%)
Osteoporotic fracture [A] *	0/53 (0%)	1/50 (2%)

	Tocilizumab	Placebo, Tocilizumab
	Affected/At Risk (%)	Affected/At Risk (%)
Pain in extremity [A] *	3/53 (5.66%)	2/50 (4%)
Rheumatoid arthritis [A] *	0/53 (0%)	1/50 (2%)
Rotator cuff syndrome [A] *	2/53 (3.77%)	0/50 (0%)
Spinal osteoarthritis [A] *	1/53 (1.89%)	0/50 (0%)
Synovitis [A] *	1/53 (1.89%)	0/50 (0%)
Tendon disorder [A] *	1/53 (1.89%)	1/50 (2%)
Tendon pain [A] *	1/53 (1.89%)	0/50 (0%)
Tendonitis [A] *	1/53 (1.89%)	0/50 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Melanocytic naevus [A] *	0/53 (0%)	1/50 (2%)
Pyogenic granuloma [A] *	1/53 (1.89%)	0/50 (0%)
Skin papilloma [A] *	1/53 (1.89%)	0/50 (0%)
Nervous system disorders		
Burning sensation [A] *	1/53 (1.89%)	1/50 (2%)
Carpal tunnel syndrome [A] *	0/53 (0%)	1/50 (2%)
Headache [A] *	7/53 (13.21%)	4/50 (8%)
Memory impairment [A] *	1/53 (1.89%)	0/50 (0%)
Migraine [A] *	1/53 (1.89%)	0/50 (0%)
Paraesthesia [A] *	4/53 (7.55%)	3/50 (6%)
Presyncope [A] *	4/53 (7.55%)	0/50 (0%)
Sciatica [A] *	3/53 (5.66%)	5/50 (10%)
Psychiatric disorders		

	Tocilizumab	Placebo, Tocilizumab
	Affected/At Risk (%)	Affected/At Risk (%)
Anxiety [A] *	3/53 (5.66%)	1/50 (2%)
Depression [A] *	2/53 (3.77%)	0/50 (0%)
Insomnia [A] *	3/53 (5.66%)	0/50 (0%)
Sleep disorder [A] *	1/53 (1.89%)	0/50 (0%)
Stress [A] *	1/53 (1.89%)	0/50 (0%)
Renal and urinary disorders		
Haematuria [A] *	0/53 (0%)	1/50 (2%)
Leukocyturia [A] *	0/53 (0%)	1/50 (2%)
Pollakiuria [A] *	1/53 (1.89%)	0/50 (0%)
Renal cyst [A] *	1/53 (1.89%)	1/50 (2%)
Renal failure [A] *	1/53 (1.89%)	0/50 (0%)
Urinary incontinence [A] *	0/53 (0%)	1/50 (2%)
Reproductive system and breast disorders		
Breast discomfort [A] *	1/53 (1.89%)	0/50 (0%)
Dyspareunia [A] *	1/53 (1.89%)	0/50 (0%)
Erectile dysfunction [A] *	1/53 (1.89%)	0/50 (0%)
Metrorrhagia [A] *	0/53 (0%)	1/50 (2%)
Respiratory, thoracic and mediastinal disorders		
Asthma [A] *	0/53 (0%)	2/50 (4%)
Bronchial obstruction [A] *	1/53 (1.89%)	0/50 (0%)
Cough [A] *	4/53 (7.55%)	4/50 (8%)
Dysphonia [A] *	0/53 (0%)	1/50 (2%)

	Tocilizumab	Placebo, Tocilizumab
	Affected/At Risk (%)	Affected/At Risk (%)
Interstitial lung disease [A] *	0/53 (0%)	1/50 (2%)
Pulmonary fibrosis [A] *	0/53 (0%)	1/50 (2%)
Rhinitis allergic [A] *	1/53 (1.89%)	0/50 (0%)
Skin and subcutaneous tissue disorders		
Acne [A] *	1/53 (1.89%)	0/50 (0%)
Alopecia [A] *	1/53 (1.89%)	3/50 (6%)
Dermal cyst [A] *	1/53 (1.89%)	0/50 (0%)
Dermatitis allergic [A] *	0/53 (0%)	1/50 (2%)
Dermatitis psoriasiform [A] *	0/53 (0%)	1/50 (2%)
Dry skin [A] *	0/53 (0%)	2/50 (4%)
Dyshidrosis [A] *	1/53 (1.89%)	0/50 (0%)
Ecchymosis [A] *	0/53 (0%)	1/50 (2%)
Eczema [A] *	2/53 (3.77%)	3/50 (6%)
Erythema [A] *	3/53 (5.66%)	0/50 (0%)
Hyperhidrosis [A] *	0/53 (0%)	1/50 (2%)
Hypotrichosis [A] *	0/53 (0%)	1/50 (2%)
Mechanical urticaria [A] *	1/53 (1.89%)	0/50 (0%)
Nail bed inflammation [A] *	1/53 (1.89%)	0/50 (0%)
Night sweats [A] *	1/53 (1.89%)	0/50 (0%)
Pruritus [A] *	2/53 (3.77%)	4/50 (8%)
Pruritus allergic [A] *	1/53 (1.89%)	1/50 (2%)
Purpura [A] *	1/53 (1.89%)	0/50 (0%)

	Tocilizumab	Placebo, Tocilizumab
	Affected/At Risk (%)	Affected/At Risk (%)
Rash [A] *	2/53 (3.77%)	2/50 (4%)
Rash papular [A] *	0/53 (0%)	1/50 (2%)
Rash pruritic [A] *	1/53 (1.89%)	1/50 (2%)
Seborrhoeic dermatitis [A] *	0/53 (0%)	1/50 (2%)
Skin erosion [A] *	1/53 (1.89%)	0/50 (0%)
Urticaria [A] *	1/53 (1.89%)	0/50 (0%)
Surgical and medical procedures		
Cerumen removal [A] *	1/53 (1.89%)	0/50 (0%)
Gingival operation [A] *	0/53 (0%)	1/50 (2%)
Tooth extraction [A] *	1/53 (1.89%)	0/50 (0%)
Vascular disorders		
Haematoma [A] *	1/53 (1.89%)	0/50 (0%)
Hot flush [A] *	0/53 (0%)	3/50 (6%)
Hypertension [A] *	1/53 (1.89%)	4/50 (8%)
Hypotension [A] *	1/53 (1.89%)	1/50 (2%)
Phlebitis [A] *	1/53 (1.89%)	0/50 (0%)
Thrombophlebitis [A] *	1/53 (1.89%)	0/50 (0%)
Venous insufficiency [A] *	1/53 (1.89%)	0/50 (0%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The study being conducted under this agreement is part of the overall study. Investigator is free to publish in reputable journals or to present at professional conferences the results of the study, but after the first publication or presentation that involves the overall study. Sponsor may request that confidential information be deleted and/or the publication be postponed in order to protect the Sponsor's intellectual property rights.

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