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Trial record **2 of 2** for: CAIN457C2303

Previous Study | Return to List | Next Study

Phase III Study in Refractory Behcet's Disease (SHIELD)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT00995709

First received: October 13, 2009
Last updated: August 13, 2015
Last verified: August 2015
History of Changes

Full Text View | Tabular View | **Study Results** | Disclaimer | How to Read a Study Record

Results First Received: February 12, 2015

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Behcet Disease
Interventions:	Drug: AIN457 Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
AIN457C 300 mg Every 2 Week Dosage Regimen	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each.
AIN457C 300 mg Monthly Dosage Regimen	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each. One patient in the AIN457 300 mg monthly group (PID 0161/00002) was randomized; however, this patient did not meet eligibility criteria and never received study medication
Placebo to AIN457C	Placebo was administered in 2 s.c. injections

Participant Flow: Overall Study

	AIN457C 300 mg Every 2 Week Dosage Regimen	AIN457C 300 mg Monthly Dosage Regimen	Placebo to AIN457C
STARTED	**39**	**40**	**39**
COMPLETED	**32**	**31** [1]	**34**
NOT COMPLETED	**7**	**9**	**5**
Adverse Event	**4**	**2**	**0**
Lack of Efficacy	**0**	**1**	**4**
Withdrawal by Subject	**0**	**4**	**1**
Lost to Follow-up	**1**	**0**	**0**
Death	**0**	**1**	**0**

Protocol Violation	**2**	**1**	**0**

[1] patient in the 300 mg monthly group was randomized,was not eligible,never received study medication

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
a. One patient who screen-failed was inadvertently randomized to the AIN457 300 mg monthly group. This patient did not receive any study medication.

Reporting Groups

	Description
AIN457C 300 mg Every 2 Week Dosage Regimen	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each.
AIN457C 300 mg Monthly Dosage Regimen (a)	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each
Placebo to AIN457C	Placebo was administered in 2 s.c. injections
Total	Total of all reporting groups

Baseline Measures

	AIN457C 300 mg Every 2 Week Dosage Regimen	AIN457C 300 mg Monthly Dosage Regimen (a)	Placebo to AIN457C	Total
Number of Participants [units: participants]	**39**	**40**	**39**	**118**
Age [units: Years] Mean (Standard Deviation)	**36.2 (10.96)**	**34.0 (11.86)**	**32.5 (10.34)**	**34.2 (11.09)**
Gender [units: Participants]				

Female	**12**	**11**	**15**	**38**
Male	**27**	**29**	**24**	**80**
Ethnicity (NIH/OMB) [units: participants]				
Hispanic or Latino	**0**	**0**	**1**	**1**
Not Hispanic or Latino	**39**	**39**	**37**	**115**
Unknown or Not Reported	**0**	**1**	**1**	**2**
Region of Enrollment [units: Participants]				
France	**1**	**0**	**0**	**1**
Turkey	**19**	**18**	**18**	**55**
Germany	**1**	**1**	**1**	**3**
Greece	**3**	**5**	**4**	**12**
Italy	**3**	**2**	**2**	**7**
Spain	**1**	**0**	**1**	**2**
United States	**0**	**2**	**0**	**2**
Egypt	**1**	**2**	**2**	**5**
Israel	**2**	**0**	**1**	**3**
Jordan	**0**	**2**	**1**	**3**
Tunisia	**2**	**1**	**2**	**5**
Hong Kong	**1**	**1**	**1**	**3**
India	**1**	**2**	**1**	**4**
Korea, Republic Of	**2**	**4**	**4**	**10**
Singapore	**1**	**0**	**1**	**2**
Taiwan, Province Of	**1**	**0**	**0**	**1**

China				

Outcome Measures

Hide All Outcome Measures

1. Primary: Rate of Recurrent Ocular Exacerbations in the Study Eye During 24 Weeks by Treatment [Time Frame: Baseline to week 24]

Measure Type	Primary
Measure Title	Rate of Recurrent Ocular Exacerbations in the Study Eye During 24 Weeks by Treatment
Measure Description	No text entered.
Time Frame	Baseline to week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set

Reporting Groups

	Description
AIN457C 300 mg Every 2 Week Dosage Regimen	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each.
AIN457C 300 mg Monthly Dosage Regimen (a)	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each
Placebo to AIN457C	Placebo was administered in 2 s.c. injections

Measured Values

	AIN457C 300 mg Every 2 Week Dosage Regimen	**AIN457C 300 mg Monthly Dosage Regimen (a)**	**Placebo to AIN457C**

Number of Participants Analyzed [units: participants]	**39**	**39**	**39**
Rate of Recurrent Ocular Exacerbations in the Study Eye During 24 Weeks by Treatment [units: Ocular Exacerbations] Mean (Standard Deviation)	**7.7 (22.40)**	**11.5 (28.19)**	**7.7 (22.35)**

No statistical analysis provided for Rate of Recurrent Ocular Exacerbations in the Study Eye During 24 Weeks by Treatment

2. Primary: Rate of Recurrent Ocular Exacerbations in the Study Eye During 24 Weeks by Treatment [Time Frame: 24 weeks]

Measure Type	Primary
Measure Title	Rate of Recurrent Ocular Exacerbations in the Study Eye During 24 Weeks by Treatment
Measure Description	Patients number of occurences during a 24 week period.
Time Frame	24 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set

Reporting Groups

	Description
AIN457C 300 mg Every 2 Week Dosage Regimen	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each.
AIN457C 300 mg Monthly Dosage Regimen (a)	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each
Placebo to AIN457C	Placebo was administered in 2 s.c. injections

Measured Values

	AIN457C 300 mg Every 2 Week Dosage Regimen	AIN457C 300 mg Monthly Dosage Regimen (a)	Placebo to AIN457C
Number of Participants Analyzed [units: participants]	**39**	**39**	**39**
Rate of Recurrent Ocular Exacerbations in the Study Eye During 24 Weeks by Treatment [units: Participants]			
0 recurrences	**15**	**15**	**11**
1 recurrence	**8**	**14**	**13**
2 recurrences	**8**	**3**	**5**
3 or more recurrences	**8**	**7**	**10**

No statistical analysis provided for Rate of Recurrent Ocular Exacerbations in the Study Eye During 24 Weeks by Treatment

3. Secondary: Change From Baseline for Composite Immunosuppressive Medication Score at Week 24 by Treatment (Full Analysis Set) [Time Frame: 24 weeks]

Measure Type	Secondary
Measure Title	Change From Baseline for Composite Immunosuppressive Medication Score at Week 24 by Treatment (Full Analysis Set)
Measure Description	For each corticosteroid medication, dose of the corticosteroid was first converted to a prednisone-equivalent dose. To determine the prednisone equivalent dose, the corticosteroid dose was multiplied by a conversion factor. . The total prednisone equivalent dose was calculated as the sum of the prednisone equivalent doses of all corticosteroids. Consequently, the total converted prednisone equivalent dose was used to obtain the immunosuppressive score. The key secondary efficacy variable was the change in total post-baseline immunosuppressive medication score from baseline.The score is actually the prednisoone equivalents taken by patient as calculated by conversion table. A reduction in prenisone or prenisone equivalents is a positive outcome. An increase in the number of prednisone equivalents suggests that the treatment is not efficacious or that there is disease progression. A score of 0 would be the lowest (no steriods taken) and the upper limit is indeterminate.
Time Frame	24 weeks

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set

Reporting Groups

	Description
AIN457C 300 mg Every 2 Week Dosage Regimen	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each.
AIN457C 300 mg Monthly Dosage Regimen (a)	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each
Placebo to AIN457C	Placebo was administered in 2 s.c. injections

Measured Values

	AIN457C 300 mg Every 2 Week Dosage Regimen	**AIN457C 300 mg Monthly Dosage Regimen (a)**	**Placebo to AIN457C**
Number of Participants Analyzed [units: participants]	**39**	**39**	**39**
Change From Baseline for Composite Immunosuppressive Medication Score at Week 24 by Treatment (Full Analysis Set) [units: immunosuppressive medication score] Mean (Standard Deviation)			
Baseline Score (n=39,39,39)	**7.769 (4.306)**	**10.11 (5.3236)**	**9.231 (3.8064)**
Week 24 (n=34,32,34)	**7.441 (4.4641)**	**10.09 (5.3331)**	**8.722 (3.2027)**
LOCF (n=39,39,39)	**7.769 (4.3036)**	**10.11 (5.3236)**	**9.231 (3.8064)**

No statistical analysis provided for Change From Baseline for Composite Immunosuppressive Medication Score at Week 24 by Treatment (Full Analysis Set)

4. Secondary: To Determine the Effect of AIN457 on Macular Edema and Visual Acuity in Patients With Posterior Segment Uveitis Secondary to Behçet's Disease as Determined by Optical Coherence Tomography. [Time Frame: baseline, and wk 24 (end of study)]

Measure Type	Secondary
Measure Title	To Determine the Effect of AIN457 on Macular Edema and Visual Acuity in Patients With Posterior Segment Uveitis Secondary to Behçet's Disease as Determined by Optical Coherence Tomography.
Measure Description	Optical coherence tomography (OCT) is amedical imaging technique that uses light to capture micrometer-resolution, three-dimensional images from within optical scattering media (e.g., biological tissue). OCT is based on low-coherence interferometry, typically employing near-infrared light. The use of relatively long wavelength light allows it to penetrate into the scattering medium. OCT is a noninvasive procedure that uses optical interferometry to visualize the structures within the retina. Following dilation of the pupil, a light source operating at 850nm provides probe illumination which is split and detected with and without the refraction of the retinal tissues. Cross-sectional imaging is accomplished in 1.3 second by acquiring a sequence of interferometric A-scans. A false color tomogram of optical reflectivity is produced by the computer. Central foveal thickness will be the primary variable derived from OCT. A increase in thickness could translate to disease progression.
Time Frame	baseline, and wk 24 (end of study)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
(Full Analysis Set)

Reporting Groups

	Description
AIN457C 300 mg Every 2 Week Dosage Regimen	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each.
AIN457C 300 mg Monthly Dosage Regimen (a)	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each
Placebo to AIN457C	Placebo was administered in 2 s.c. injections

Measured Values

	AIN457C 300 mg Every 2 Week Dosage Regimen	AIN457C 300 mg Monthly Dosage Regimen (a)	Placebo to AIN457C
Number of Participants Analyzed [units: participants]	**39**	**39**	**39**
To Determine the Effect of AIN457 on Macular Edema and Visual Acuity in Patients With Posterior Segment Uveitis Secondary to Behçet's Disease as Determined by Optical Coherence Tomography. [units: change from baseline : micrometers] Mean (Standard Deviation)	**-26.5 (131.32)**	**3.6 (75.29)**	**-49.4 (174.25)**

No statistical analysis provided for To Determine the Effect of AIN457 on Macular Edema and Visual Acuity in Patients With Posterior Segment Uveitis Secondary to Behçet's Disease as Determined by Optical Coherence Tomography.

5. Secondary: To Establish the Impact of AIN457 on Quality of Life of Posterior Segment Uveitis Patients Secondary to Behçet's Disease Refractory to Systemic Immunomodulatory Therapy as Measured by National Eye Institute Visual Function Questionaire-25 and Euroqol. [Time Frame: screening, and wk 24 (end of study)]

Measure Type	Secondary
Measure Title	To Establish the Impact of AIN457 on Quality of Life of Posterior Segment Uveitis Patients Secondary to Behçet's Disease Refractory to Systemic Immunomodulatory Therapy as Measured by National Eye Institute Visual Function Questionaire-25 and Euroqol.
Measure Description	The VFQ-25 is a reliable and valid 25-item version of the 51-item National Eye Institute Visual Function Questionnaire (NEI-VFQ). It is especially useful in settings such as clinical trials, where interview length is a critical consideration. Scores range from 0 to 100, with higher scores indicating better visual function.
Time Frame	screening, and wk 24 (end of study)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method.

Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set

Reporting Groups

	Description
AIN457C 300 mg Every 2 Week Dosage Regimen	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each.
AIN457C 300 mg Monthly Dosage Regimen (a)	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each
Placebo to AIN457C	Placebo was administered in 2 s.c. injections

Measured Values

	AIN457C 300 mg Every 2 Week Dosage Regimen	**AIN457C 300 mg Monthly Dosage Regimen (a)**	**Placebo to AIN457C**
Number of Participants Analyzed **[units: participants]**	**39**	**39**	**39**
To Establish the Impact of AIN457 on Quality of Life of Posterior Segment Uveitis Patients Secondary to Behçet's Disease Refractory to Systemic Immunomodulatory Therapy as Measured by National Eye Institute Visual Function Questionaire-25 and Euroqol. **[units: Score]** **Mean (Standard Deviation)**			
Baseline (n= 38,35,39)	**62.46 (21.817)**	**64.17 (25.549)**	**62.11 (24.416)**
Week 24 (n=38,35,38)	**66.09 (24.295)**	**73.68 (22.634)**	**69.29 (21.858)**

No statistical analysis provided for To Establish the Impact of AIN457 on Quality of Life of Posterior Segment Uveitis Patients Secondary to Behçet's Disease Refractory to Systemic Immunomodulatory Therapy as Measured by National Eye Institute Visual Function Questionaire-25 and Euroqol.

6. Secondary: To Observe the Effect of AIN457 on the Systemic Non-ocular Manifestations of Behçet's Disease in Patients With Posterior Segment Uveitis Requiring Systemic Immunosuppression as Measured by the Bechet's Disease Current Activity Form. [Time Frame: baseline and wk 24 (end of study)]

Measure Type	Secondary
Measure Title	To Observe the Effect of AIN457 on the Systemic Non-ocular Manifestations of Behçet's Disease in Patients With Posterior Segment Uveitis Requiring Systemic Immunosuppression as Measured by the Bechet's Disease Current Activity Form.
Measure Description	The BDCAF scores oral and genital ulceration, skin, joint and gastrointestinal involvement, presence of fatigue and headache according to the duration of symptoms. The presence and type of large-vessel and central nervous system (CNS) involvement are documented. Eye activity was deemed present if there was a history of blurring of vision or if the eye was painful or red. . The BDCAF score was calculated by adding the score of each index and ranged between 0 and 12 A reduction in score signifies a lessening of the disease.
Time Frame	baseline and wk 24 (end of study)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis set

Reporting Groups

	Description
AIN457C 300 mg Every 2 Week Dosage Regimen	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each.
AIN457C 300 mg Monthly Dosage Regimen (a)	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each
Placebo to AIN457C	Placebo was administered in 2 s.c. injections

Measured Values

	AIN457C 300 mg Every 2 Week Dosage Regimen	AIN457C 300 mg Monthly Dosage Regimen (a)	Placebo to AIN457C
Number of Participants Analyzed **[units: participants]**	**16**	**17**	**19**
To Observe the Effect of AIN457 on the Systemic Non-ocular Manifestations of Behçet's Disease in Patients With Posterior Segment Uveitis Requiring Systemic Immunosuppression as Measured by the Bechet's Disease Current Activity Form. **[units: change from baseline score]** **Mean (Standard Deviation)**	**-1.3 (1.81)**	**-1.7 (1.49)**	**-1.1 (1.22)**

No statistical analysis provided for To Observe the Effect of AIN457 on the Systemic Non-ocular Manifestations of Behçet's Disease in Patients With Posterior Segment Uveitis Requiring Systemic Immunosuppression as Measured by the Bechet's Disease Current Activity Form.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
AIN457 300mg Every 2 Weeks	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each.
AIN457 300mg Monthly	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each.
Placebo	Placebo was administered in 2 s.c. injections

Serious Adverse Events

	AIN457 300mg Every 2 Weeks	AIN457 300mg Monthly	Placebo

Total, serious adverse events			
# participants affected / at risk	**6/39 (15.38%)**	**8/39 (20.51%)**	**5/39 (12.82%)**
Cardiac disorders			
Supraventricular tachycardia †1			
# participants affected / at risk	**1/39 (2.56%)**	**0/39 (0.00%)**	**0/39 (0.00%)**
Ear and labyrinth disorders			
Vertigo †1			
# participants affected / at risk	**0/39 (0.00%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
Eye disorders			
Cataract cortical (Fellow eye) †1			
# participants affected / at risk	**0/39 (0.00%)**	**0/39 (0.00%)**	**1/39 (2.56%)**
Cataract nuclear (Fellow eye) †1			
# participants affected / at risk	**0/39 (0.00%)**	**0/39 (0.00%)**	**1/39 (2.56%)**
Cataract subcapsular (Fellow eye) †1			
# participants affected / at risk	**0/39 (0.00%)**	**0/39 (0.00%)**	**1/39 (2.56%)**
Choroiditis (Fellow eye) †1			
# participants affected / at risk	**1/39 (2.56%)**	**0/39 (0.00%)**	**0/39 (0.00%)**
Glaucoma (Fellow eye) †1			
# participants affected / at risk	**0/39 (0.00%)**	**0/39 (0.00%)**	**1/39 (2.56%)**
Retinal infiltrates (Fellow eye) †1			
# participants affected / at risk	**1/39 (2.56%)**	**0/39 (0.00%)**	**0/39 (0.00%)**
Retinal infiltrates (Study eye) †1			
# participants affected / at risk	**1/39 (2.56%)**	**0/39 (0.00%)**	**0/39 (0.00%)**
Uveitis (Fellow eye) †1			
# participants affected / at risk	**1/39 (2.56%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
Uveitis (Study eye) †1			
# participants affected / at risk	**0/39 (0.00%)**	**1/39 (2.56%)**	**1/39 (2.56%)**
Gastrointestinal disorders			

Abdominal pain [†1]			
# participants affected / at risk	**0/39 (0.00%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
Aphthous stomatitis [†1]			
# participants affected / at risk	**0/39 (0.00%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
Diarrhoea [†1]			
# participants affected / at risk	**0/39 (0.00%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
Diarrhoea haemorrhagic [†1]			
# participants affected / at risk	**0/39 (0.00%)**	**0/39 (0.00%)**	**1/39 (2.56%)**
Haematemesis [†1]			
# participants affected / at risk	**0/39 (0.00%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
Lower gastrointestinal haemorrhage [†1]			
# participants affected / at risk	**0/39 (0.00%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
General disorders			
Fatigue [†1]			
# participants affected / at risk	**1/39 (2.56%)**	**0/39 (0.00%)**	**0/39 (0.00%)**
Immune system disorders			
Behcet's syndrome [†1]			
# participants affected / at risk	**0/39 (0.00%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
Behcet's syndrome (Fellow eye) [†1]			
# participants affected / at risk	**0/39 (0.00%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
Behcet's syndrome (Study eye) [†1]			
# participants affected / at risk	**0/39 (0.00%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
Infections and infestations			
Folliculitis [†1]			
# participants affected / at risk	**2/39 (5.13%)**	**0/39 (0.00%)**	**0/39 (0.00%)**
Hypopyon (Fellow eye) [†1]			
# participants affected / at risk	**1/39 (2.56%)**	**0/39 (0.00%)**	**0/39 (0.00%)**
Urinary tract infection [†1]			

# participants affected / at risk	**1/39 (2.56%)**	**0/39 (0.00%)**	**0/39 (0.00%)**
Investigations			
Intraocular pressure increased (Fellow eye) †1			
# participants affected / at risk	**0/39 (0.00%)**	**0/39 (0.00%)**	**1/39 (2.56%)**
Weight decreased †1			
# participants affected / at risk	**1/39 (2.56%)**	**0/39 (0.00%)**	**0/39 (0.00%)**
Metabolism and nutrition disorders			
Diabetes mellitus †1			
# participants affected / at risk	**0/39 (0.00%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
Musculoskeletal and connective tissue disorders			
Bone pain †1			
# participants affected / at risk	**0/39 (0.00%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
Renal and urinary disorders			
Nephrolithiasis †1			
# participants affected / at risk	**1/39 (2.56%)**	**0/39 (0.00%)**	**0/39 (0.00%)**
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism †1			
# participants affected / at risk	**0/39 (0.00%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
Skin and subcutaneous tissue disorders			
Skin lesion †1			
# participants affected / at risk	**0/39 (0.00%)**	**1/39 (2.56%)**	**0/39 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
AIN457 300mg Every 2 Weeks	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each.
AIN457 300mg Monthly	AIN457 300 mg was administered in 2 subcutaneous (s.c.) injections of 150 mg each.
Placebo	Placebo was administered in 2 s.c. injections

Other Adverse Events

	AIN457 300mg Every 2 Weeks	AIN457 300mg Monthly	Placebo
Total, other (not including serious) adverse events			
# participants affected / at risk	**28/39 (71.79%)**	**25/39 (64.10%)**	**22/39 (56.41%)**
Eye disorders			
Cataract subcapsular (Fellow eye) †1			
# participants affected / at risk	**3/39 (7.69%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
Cataract subcapsular (Study eye) †1			
# participants affected / at risk	**4/39 (10.26%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
Eye pain (Study eye) †1			
# participants affected / at risk	**1/39 (2.56%)**	**2/39 (5.13%)**	**2/39 (5.13%)**
Retinal vasculitis (Study eye) †1			
# participants affected / at risk	**2/39 (5.13%)**	**0/39 (0.00%)**	**0/39 (0.00%)**
Vision blurred (Fellow eye) †1			

# participants affected / at risk	0/39 (0.00%)	6/39 (15.38%)	1/39 (2.56%)
Vision blurred (Study eye) [†1]			
# participants affected / at risk	0/39 (0.00%)	1/39 (2.56%)	3/39 (7.69%)
Visual acuity reduced (Study eye) [†1]			
# participants affected / at risk	4/39 (10.26%)	2/39 (5.13%)	1/39 (2.56%)
Gastrointestinal disorders			
Abdominal pain [†1]			
# participants affected / at risk	1/39 (2.56%)	0/39 (0.00%)	2/39 (5.13%)
Abdominal pain upper [†1]			
# participants affected / at risk	2/39 (5.13%)	2/39 (5.13%)	1/39 (2.56%)
Aphthous stomatitis [†1]			
# participants affected / at risk	3/39 (7.69%)	2/39 (5.13%)	0/39 (0.00%)
Diarrhoea [†1]			
# participants affected / at risk	0/39 (0.00%)	3/39 (7.69%)	1/39 (2.56%)
Mouth ulceration [†1]			
# participants affected / at risk	0/39 (0.00%)	0/39 (0.00%)	2/39 (5.13%)
Nausea [†1]			
# participants affected / at risk	4/39 (10.26%)	3/39 (7.69%)	2/39 (5.13%)
Toothache [†1]			
# participants affected / at risk	2/39 (5.13%)	1/39 (2.56%)	0/39 (0.00%)
Vomiting [†1]			
# participants affected / at risk	2/39 (5.13%)	0/39 (0.00%)	3/39 (7.69%)
General disorders			
Fatigue [†1]			
# participants affected / at risk	2/39 (5.13%)	2/39 (5.13%)	4/39 (10.26%)
Non-cardiac chest pain [†1]			
# participants affected / at risk	2/39 (5.13%)	0/39 (0.00%)	1/39 (2.56%)
Oedema peripheral [†1]			

# participants affected / at risk	3/39 (7.69%)	1/39 (2.56%)	0/39 (0.00%)
Pyrexia †1			
# participants affected / at risk	6/39 (15.38%)	2/39 (5.13%)	4/39 (10.26%)
Infections and infestations			
Conjunctivitis infective (Study eye) †1			
# participants affected / at risk	1/39 (2.56%)	2/39 (5.13%)	1/39 (2.56%)
Influenza †1			
# participants affected / at risk	2/39 (5.13%)	4/39 (10.26%)	1/39 (2.56%)
Nasopharyngitis †1			
# participants affected / at risk	1/39 (2.56%)	2/39 (5.13%)	1/39 (2.56%)
Rash pustular †1			
# participants affected / at risk	2/39 (5.13%)	0/39 (0.00%)	1/39 (2.56%)
Sinusitis †1			
# participants affected / at risk	0/39 (0.00%)	2/39 (5.13%)	1/39 (2.56%)
Upper respiratory tract infection †1			
# participants affected / at risk	3/39 (7.69%)	4/39 (10.26%)	1/39 (2.56%)
Urinary tract infection †1			
# participants affected / at risk	1/39 (2.56%)	0/39 (0.00%)	2/39 (5.13%)
Investigations			
Blood glucose increased †1			
# participants affected / at risk	0/39 (0.00%)	2/39 (5.13%)	0/39 (0.00%)
Intraocular pressure increased (Study eye) †1			
# participants affected / at risk	2/39 (5.13%)	2/39 (5.13%)	0/39 (0.00%)
Musculoskeletal and connective tissue disorders			
Arthralgia †1			
# participants affected / at risk	4/39 (10.26%)	3/39 (7.69%)	3/39 (7.69%)
Pain in extremity †1			
# participants affected / at risk	3/39 (7.69%)	1/39 (2.56%)	1/39 (2.56%)

Nervous system disorders			
Dizziness †1			
# participants affected / at risk	**0/39 (0.00%)**	**3/39 (7.69%)**	**0/39 (0.00%)**
Headache †1			
# participants affected / at risk	**9/39 (23.08%)**	**6/39 (15.38%)**	**9/39 (23.08%)**
Psychiatric disorders			
Anxiety †1			
# participants affected / at risk	**0/39 (0.00%)**	**3/39 (7.69%)**	**0/39 (0.00%)**
Respiratory, thoracic and mediastinal disorders			
Dyspnoea †1			
# participants affected / at risk	**2/39 (5.13%)**	**0/39 (0.00%)**	**0/39 (0.00%)**
Skin and subcutaneous tissue disorders			
Erythema †1			
# participants affected / at risk	**1/39 (2.56%)**	**1/39 (2.56%)**	**2/39 (5.13%)**
Hirsutism †1			
# participants affected / at risk	**2/39 (5.13%)**	**0/39 (0.00%)**	**1/39 (2.56%)**
Skin lesion †1			
# participants affected / at risk	**0/39 (0.00%)**	**0/39 (0.00%)**	**2/39 (5.13%)**
Vascular disorders			
Hypertension †1			
# participants affected / at risk	**1/39 (2.56%)**	**2/39 (5.13%)**	**0/39 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. ☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (ie, data from all sites) in the clinical trial

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300

No publications provided by Novartis

Publications automatically indexed to this study:

Dick AD, Tugal-Tutkun I, Foster S, Zierhut M, Melissa Liew SH, Bezlyak V, Androudi S. Secukinumab in the treatment of noninfectious uveitis: results of three randomized, controlled clinical trials. Ophthalmology. 2013 Apr;120(4):777-87. doi: 10.1016/j.ophtha.2012.09.040. Epub 2013 Jan 3.

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