A Phase 2 Study of Interferon Beta-1a (Avonex®) in Ulcerative Colitis

This study has been completed.

Sponsor:
Biogen Idec

Information provided by (Responsible Party):
Biogen Idec

ClinicalTrials.gov Identifier:
NCT00616434

First received: February 5, 2008
Last updated: July 23, 2014
Last verified: July 2014
History of Changes

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Results First Received: July 23, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver); Primary Purpose: Treatment
Condition:	Active Ulcerative Colitis
Interventions:	Drug: BG9418 (Interferon beta-1a) 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
Interferon Beta-1a	Interferon beta-1a 30 µg intramuscular (IM) injection twice weekly for 12 weeks
Placebo	Placebo IM injection twice weekly for 12 weeks

Participant Flow: Overall Study

	Interferon Beta-1a	Placebo
STARTED	62	61
COMPLETED	56	53
NOT COMPLETED	6	8
Adverse Event	5	2

Physician Decision	0	4
Withdrawal by Subject	1	1
Protocol deviation	0	1

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.
No text entered.

Reporting Groups

	Description
Interferon Beta-1a	Interferon beta-1a 30 µg intramuscular (IM) injection twice weekly for 12 weeks
Placebo	Placebo IM injection twice weekly for 12 weeks
Total	Total of all reporting groups

Baseline Measures

	Interferon Beta-1a	Placebo	Total
Number of Participants [units: participants]	62	61	123
Age [units: years] Mean (Full Range)	41.1 (21 to 64)	41.0 (20 to 65)	41.0 (20 to 65)
Gender [units: participants]			
Female	19	26	45
Male	43	35	78

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants With a Clinical Response [Time Frame: Baseline and Week 8]

Measure Type	Primary
Measure Title	Percentage of Participants With a Clinical Response
Measure Description	Clinical response is defined as a decrease from baseline in the total Mayo score of at least 3 points and at least 30%, accompanied by a decrease in the subscore for rectal bleeding of at least 1 point or an absolute subscore of 1 or less. Baseline was defined as the score collected during the screening period. The Mayo Score/Disease Activity Index (DAI) measures disease activity through assessment of 4 items: stool frequency, rectal bleeding, endoscopy findings, and Physician Global Assessment (PGA). Each item of the score is assessed on a 4-point scale, 0, 1, 2, or 3, with a higher score representing greater severity. In this study, the endoscopy subscore was expanded to a 5-point scale to increase sensitivity in this important dimension of the disease (0=normal/inactive disease, 4=deep ulceration). The Total Mayo Score can therefore range from 0 to13 points.
Time Frame	

	Baseline and Week 8
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.
Intent-to-treat (ITT): Defined as all randomized participants who received at least one dose of study treatment for whom a baseline measure was available.

Reporting Groups

	Description
Interferon Beta-1a	Interferon beta-1a 30 µg intramuscular (IM) injection twice weekly for 12 weeks
Placebo	Placebo IM injection twice weekly for 12 weeks

Measured Values

	Interferon Beta-1a	Placebo
Number of Participants Analyzed [units: participants]	62	61
Percentage of Participants With a Clinical Response [units: percentage of participants]	53	44

No statistical analysis provided for Percentage of Participants With a Clinical Response

2. Secondary: Number of Participants With Adverse Events (AEs) [Time Frame: Up to 16 weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Adverse Events (AEs)
Measure Description	An AE is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE, can therefore, be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. All AE's were analyzed based on the principle of treatment emergence. An AE was regarded as treatment-emergent if it was not present prior to receiving the first injection but subsequently appeared, or if it was present prior to receiving the first injection and subsequently worsened in severity.
Time Frame	Up to 16 weeks
Safety Issue	Yes

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.
Safety Population; participants who were randomized and received at least one dose of study treatment.

Reporting Groups

	Description
Interferon Beta-1a	Interferon beta-1a 30 µg intramuscular (IM) injection twice weekly for 12 weeks
Placebo	Placebo IM injection twice weekly for 12 weeks

Measured Values

	Interferon Beta-1a	Placebo
Number of Participants Analyzed [units: participants]	62	61
Number of Participants With Adverse Events (AEs) [units: participants]	52	35

No statistical analysis provided for Number of Participants With Adverse Events (AEs)

3. Secondary: Percentage of Participants With a Decrease on Simple Clinical Colitis Activity Index (SCCAI) of ≥3 Points at Week 8 [Time Frame: Baseline and Week 8]

Measure Type	Secondary
Measure Title	Percentage of Participants With a Decrease on Simple Clinical Colitis Activity Index (SCCAI) of ≥3 Points at Week 8
Measure Description	The SCCAI measures disease activity as defined by both participants and examiners and includes the following 13 items: general well-being, abdominal pain, bowel frequency, stool consistency, bleeding, anorexia, nausea or vomiting, abdominal tenderness, extra-intestinal complications (eye, mouth, joint, skin), temperature, sigmoidoscopic assessment, nocturnal bowel movements, and urgency of defecation. Scores range from 0 to 19 points, and scores <2.5 have been shown to correlate with Patient-Defined Remission, and a decrease of >1.5 points from Baseline correlates with Patient-Defined Significant Improvement. Baseline is defined as the mean of the screening and visit 1 scores.
Time Frame	Baseline and Week 8
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.
Intent-to-treat (ITT): Defined as all randomized participants who received at least one dose of study treatment for whom a baseline SCCAI ≥ 3 was available.

Reporting Groups

	Description
Interferon Beta-1a	Interferon beta-1a 30 µg intramuscular (IM) injection twice weekly for 12 weeks
Placebo	Placebo IM injection twice weekly for 12 weeks

Measured Values

	Interferon Beta-1a	Placebo
Number of Participants Analyzed [units: participants]	61	61
Percentage of Participants With a Decrease on Simple Clinical Colitis Activity Index (SCCAI) of **≥3 Points at Week 8** [units: percentage of participants]	64	46

No statistical analysis provided for Percentage of Participants With a Decrease on Simple Clinical Colitis Activity Index (SCCAI) **of ≥3 Points at Week 8**

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 16 weeks
Additional Description	No text entered.

Reporting Groups

	Description
Interferon Beta-1a	Interferon beta-1a 30 µg intramuscular (IM) injection twice weekly for 12 weeks
Placebo	Placebo IM injection twice weekly for 12 weeks

Serious Adverse Events

	Interferon Beta-1a	Placebo
Total, serious adverse events		
# participants affected / at risk	1/62 (1.61%)	3/61 (4.92%)
Gastrointestinal disorders		
Colitis Ulcerative [1]		
# participants affected / at risk	1/62 (1.61%)	2/61 (3.28%)
Injury, poisoning and procedural complications		
Tibia Fracture [1]		
# participants affected / at risk	0/62 (0.00%)	1/61 (1.64%)

1 Term from vocabulary, MedDRA 12.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 16 weeks
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Interferon Beta-1a	Interferon beta-1a 30 µg intramuscular (IM) injection twice weekly for 12 weeks
Placebo	Placebo IM injection twice weekly for 12 weeks

Other Adverse Events

	Interferon Beta-1a	Placebo
Total, other (not including serious) adverse events		

# participants affected / at risk	44/62 (70.97%)	20/61 (32.79%)
Blood and lymphatic system disorders		
Anaemia [1]		
# participants affected / at risk	1/62 (1.61%)	6/61 (9.84%)
Gastrointestinal disorders		
Colitis Ulcerative [1]		
# participants affected / at risk	5/62 (8.06%)	4/61 (6.56%)
General disorders		
Influenza Like Illness [1]		
# participants affected / at risk	25/62 (40.32%)	6/61 (9.84%)
Pyrexia [1]		
# participants affected / at risk	8/62 (12.90%)	2/61 (3.28%)
Malaise [1]		
# participants affected / at risk	3/62 (4.84%)	1/61 (1.64%)
Infections and infestations		
Upper Respiratory Tract Infection [1]		
# participants affected / at risk	3/62 (4.84%)	0/61 (0.00%)
Musculoskeletal and connective tissue disorders		
Myalgia [1]		
# participants affected / at risk	4/62 (6.45%)	0/61 (0.00%)
Nervous system disorders		
Headache [1]		
# participants affected / at risk	11/62 (17.74%)	3/61 (4.92%)
Vascular disorders		
Hypertension [1]		
# participants affected / at risk	3/62 (4.84%)	0/61 (0.00%)

1 Term from vocabulary, MedDRA 12.1

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: Our agreement is subject to confidentiality but generally the PI can publish, for noncommercial purposes only, results and methods of the trial, but no other Sponsor Confidential Information. PI must give Sponsor no less than 60 days to review any manuscript for a proposed publication and must delay publication for up to an additional 90 days thereafter if Sponsor needs to file any patent application to protect any of Sponsor's intellectual property contained in the proposed publication.

Results Point of Contact:

Name/Title: Biogen Idec Study Medical Director
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No publications provided

Responsible Party:	Biogen Idec
ClinicalTrials.gov Identifier:	NCT00616434 History of Changes
Obsolete Identifiers:	NCT00750490
Other Study ID Numbers:	108UC201, 2007-004867-22
Study First Received:	February 5, 2008
Results First Received:	July 23, 2014
Last Updated:	July 23, 2014
Health Authority:	Russia: Ministry of Health of the Russian Federation Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Czech Republic: State Institute for Drug Control Slovakia: State Institute for Drug Control Hungary: National Institute of Pharmacy Canada: Health Canada United States: Food and Drug Administration