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Trial record **1 of 1** for: CSMS995BIT12

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Efficacy/Safety of Octreotide Acetate in Patients With Uncontrolled Acromegaly

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00372697

First received: September 6, 2006
Last updated: April 19, 2011
Last verified: April 2011
History of Changes

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

Results First Received: January 12, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Acromegaly
Intervention:	Drug: Octreotide acetate 30 mg suspension

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
Octreotide 30 mg Every 21 Days	Participants received octreotide 30 mg every 21 days intramuscularly (im) for 6 months, a total of 8 doses. At each study visit, octreotide was administered only after completion of all scheduled efficacy and safety evaluations for that visit. Octreotide was injected im into the right or left gluteal regions. The injections were initially administered by a trained and authorized member of the investigational team. When no study visit at the investigational site was required, the injections were given by a trained nurse or the family doctor.
Octreotide 60 mg Every 28 Days	Participants received octreotide 60 mg every 28 days intramuscularly (im) for 6 months, a total of 6 doses. Octreotide mg was administered as two 30 mg injections. At each study visit, octreotide was administered only after completion of all scheduled efficacy and safety evaluations for that visit. Octreotide was injected im into the right or left gluteal regions. The injections were initially administered by a trained and authorized member of the investigational team. When no study visit at the investigational site was required, the injections were given by a trained nurse or the family doctor.

Participant Flow: Overall Study

	Octreotide 30 mg Every 21 Days	Octreotide 60 mg Every 28 Days
STARTED	**16**	**12**
COMPLETED	**15**	**11**
NOT COMPLETED	**1**	**1**

Protocol Violation	**1**	**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
Octreotide 30 mg Every 21 Days	Participants received octreotide 30 mg every 21 days intramuscularly (im) for 6 months, a total of 8 doses. At each study visit, octreotide was administered only after completion of all scheduled efficacy and safety evaluations for that visit. Octreotide was injected im into the right or left gluteal regions. The injections were initially administered by a trained and authorized member of the investigational team. When no study visit at the investigational site was required, the injections were given by a trained nurse or the family doctor.
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Total	Total of all reporting groups

Baseline Measures

	Octreotide 30 mg Every 21 Days	Octreotide 60 mg Every 28 Days	Total
Number of Participants [units: participants]	**16**	**12**	**28**

Age [units: years] Mean (Standard Deviation)	**51.3 (12.1)**	**51.8 (15.7)**	**51.5 (13.9)**
Gender [units: participants]			
Female	**10**	**4**	**14**
Male	**6**	**8**	**14**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Growth Hormone (GH) Level From Screening to End of Study (Week 24) [Time Frame: Screening to end of study (Week 24)]

Measure Type	Primary
Measure Title	Change in Growth Hormone (GH) Level From Screening to End of Study (Week 24)
Measure Description	Growth hormone (GH) level was the average value measured in 3 blood samples collected at 15 minute intervals at each visit. GH was measured with an automated immunometric assay in a central laboratory.
Time Frame	Screening to end of study (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.
Intent-to-treat (ITT) population included all participants who received at least one dose of study medication and who had at least one post-baseline evaluation of the primary variable.

Reporting Groups

	Description
Octreotide 30 mg Every 21 Days	Participants received octreotide 30 mg every 21 days intramuscularly (im) for 6 months, a total of 8 doses. At each study visit, octreotide was administered only after completion of all scheduled efficacy and safety evaluations for that visit. Octreotide was injected im into the right or left gluteal regions. The injections were initially administered by a trained and authorized member of the investigational team. When no study visit at the investigational site was required, the injections were given by a trained nurse or the family doctor.
Octreotide 60 mg Every 28 Days	Participants received octreotide 60 mg every 28 days intramuscularly (im) for 6 months, a total of 6 doses. Octreotide mg was administered as two 30 mg injections. At each study visit, octreotide was administered only after completion of all scheduled efficacy and safety evaluations for that visit. Octreotide was injected im into the right or left gluteal regions. The injections were initially administered by a trained and authorized member of the investigational team. When no study visit at the investigational site was required, the injections were given by a trained nurse or the family doctor.

Measured Values

	Octreotide 30 mg Every 21 Days	Octreotide 60 mg Every 28 Days
Number of Participants Analyzed [units: participants]	**15**	**11**
Change in Growth Hormone (GH) Level From Screening to End of Study (Week 24) [units: µg/L] Mean (Standard Deviation)	**-1.7 (9.9)**	**-2.1 (3.6)**

No statistical analysis provided for Change in Growth Hormone (GH) Level From Screening to End of Study (Week 24)

2. Primary: Change in Insulin-like Growth Factor 1 (IGF-1) Level From Screening to End of Study (Week 24) [Time Frame: Screening to end of study (Week 24)]

Measure Type	Primary

Measure Title	Change in Insulin-like Growth Factor 1 (IGF-1) Level From Screening to End of Study (Week 24)
Measure Description	Insulin-like growth factor 1 (IGF-1) level was measured in a blood sample with an automated immunometric assay in a central laboratory.
Time Frame	Screening to end of study (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.
Intent-to-treat (ITT) population included all participants who received at least one dose of study medication and who had at least one post-baseline evaluation of the primary variable.

Reporting Groups

	Description
Octreotide 30 mg Every 21 Days	Participants received octreotide 30 mg every 21 days intramuscularly (im) for 6 months, a total of 8 doses. At each study visit, octreotide was administered only after completion of all scheduled efficacy and safety evaluations for that visit. Octreotide was injected im into the right or left gluteal regions. The injections were initially administered by a trained and authorized member of the investigational team. When no study visit at the investigational site was required, the injections were given by a trained nurse or the family doctor.
Octreotide 60 mg Every 28 Days	Participants received octreotide 60 mg every 28 days intramuscularly (im) for 6 months, a total of 6 doses. Octreotide mg was administered as two 30 mg injections. At each study visit, octreotide was administered only after completion of all scheduled efficacy and safety evaluations for that visit. Octreotide was injected im into the right or left gluteal regions. The injections were initially administered by a trained and authorized member of the investigational team. When no study visit at the investigational site was required, the injections were given by a trained nurse or the family doctor.

Measured Values

	Octreotide 30 mg Every 21 Days	**Octreotide 60 mg Every 28 Days**
Number of Participants Analyzed		

[units: participants]	**15**	**11**
Change in Insulin-like Growth Factor 1 (IGF-1) Level From Screening to End of Study (Week 24) **[units: µg/L]** **Mean (Standard Deviation)**	**-40.4 (180.2)**	**-135.0 (170.9)**

No statistical analysis provided for Change in Insulin-like Growth Factor 1 (IGF-1) Level From Screening to End of Study (Week 24)

3. Secondary: Change in Tumor Volume From Screening to End of Study (Week 24) [Time Frame: Screening to end of study (Week 24)]

Measure Type	Secondary
Measure Title	Change in Tumor Volume From Screening to End of Study (Week 24)
Measure Description	A pre-treatment magnetic resonance image (MRI) assessment of the pituitary area was required within 12 weeks prior to Screening as a baseline evaluation. A second MRI was performed at the end of the study (Week 24). All MRIs were performed according to protocol-defined guidelines. The tumor volume (mm^3) was calculated from measurements obtained in 3 axes from the MRI images.
Time Frame	Screening to end of study (Week 24)
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.
Intent-to-treat (ITT) population included all enrolled participants who received at least 1 dose of assigned study medication and who had data for this outcome measure.

Reporting Groups

	Description

Octreotide 30 mg Every 21 Days	Participants received octreotide 30 mg every 21 days intramuscularly (im) for 6 months, a total of 8 doses. At each study visit, octreotide was administered only after completion of all scheduled efficacy and safety evaluations for that visit. Octreotide was injected im into the right or left gluteal regions. The injections were initially administered by a trained and authorized member of the investigational team. When no study visit at the investigational site was required, the injections were given by a trained nurse or the family doctor.
Octreotide 60 mg Every 28 Days	Participants received octreotide 60 mg every 28 days intramuscularly (im) for 6 months, a total of 6 doses. Octreotide mg was administered as two 30 mg injections. At each study visit, octreotide was administered only after completion of all scheduled efficacy and safety evaluations for that visit. Octreotide was injected im into the right or left gluteal regions. The injections were initially administered by a trained and authorized member of the investigational team. When no study visit at the investigational site was required, the injections were given by a trained nurse or the family doctor.

Measured Values

	Octreotide 30 mg Every 21 Days	**Octreotide 60 mg Every 28 Days**
Number of Participants Analyzed [units: participants]	**14**	**9**
Change in Tumor Volume From Screening to End of Study (Week 24) [units: mm^3] Mean (Standard Deviation)	**15.9 (91.8)**	**-0.4 (21.0)**

No statistical analysis provided for Change in Tumor Volume From Screening to End of Study (Week 24)

4. Secondary: Percentage of Participants With > 20% Tumor Shrinkage From Screening to End of Study (Week 24) [Time Frame: Screening to end of study (Week 24)]

Measure Type	Secondary
Measure Title	Percentage of Participants With > 20% Tumor Shrinkage From Screening to End of Study (Week 24)
Measure Description	A pre-treatment magnetic resonance image (MRI) assessment of the pituitary area was required within 12 weeks prior

	to Screening as a baseline evaluation. A second MRI was performed at the end of the study (Week 24). All MRIs were performed according to protocol-defined guidelines. The tumor volume (mm^3) was calculated from measurements obtained in 3 axes from the MRI images.
Time Frame	Screening to end of study (Week 24)
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.
Intent-to-treat (ITT) population included all enrolled participants who received at least 1 dose of assigned study medication and who had data for this outcome measure.

Reporting Groups

	Description
Octreotide 30 mg Every 21 Days	Participants received octreotide 30 mg every 21 days intramuscularly (im) for 6 months, a total of 8 doses. At each study visit, octreotide was administered only after completion of all scheduled efficacy and safety evaluations for that visit. Octreotide was injected im into the right or left gluteal regions. The injections were initially administered by a trained and authorized member of the investigational team. When no study visit at the investigational site was required, the injections were given by a trained nurse or the family doctor.
Octreotide 60 mg Every 28 Days	Participants received octreotide 60 mg every 28 days intramuscularly (im) for 6 months, a total of 6 doses. Octreotide mg was administered as two 30 mg injections. At each study visit, octreotide was administered only after completion of all scheduled efficacy and safety evaluations for that visit. Octreotide was injected im into the right or left gluteal regions. The injections were initially administered by a trained and authorized member of the investigational team. When no study visit at the investigational site was required, the injections were given by a trained nurse or the family doctor.

Measured Values

	Octreotide 30 mg Every 21 Days	**Octreotide 60 mg Every 28 Days**
Number of Participants Analyzed [units: participants]	**14**	**9**

Percentage of Participants With > 20% Tumor Shrinkage From Screening to End of Study (Week 24) [units: Percentage of participants]	**14.3**	**11.1**

No statistical analysis provided for Percentage of Participants With > 20% Tumor Shrinkage From Screening to End of Study (Week 24)

5. Secondary: Percentage of Participants Asymptomatic for Acromegaly Symptoms at Week 12 and End of Study (Week 24) [Time Frame: Week 12 and end of study (Week 24)]

Measure Type	Secondary
Measure Title	Percentage of Participants Asymptomatic for Acromegaly Symptoms at Week 12 and End of Study (Week 24)
Measure Description	The investigator asked the participant to score the following symptoms of acromegaly: Headache, perspiration, paresthesia, fatigue, osteoarthralgia, and carpal tunnel syndrome on a 5-point scale (0=absent; 1=mild; 2=moderate; 3=severe, but not disabling; 4=severe and disabling). The percentage of asymptomatic participants, ie, with a score of 0 for all symptoms, was calculated.
Time Frame	Week 12 and end of study (Week 24)
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.
Intent-to-treat (ITT) population included all enrolled participants who received at least 1 dose of assigned study medication.

Reporting Groups

	Description
Octreotide 30 mg Every 21 Days	Participants received octreotide 30 mg every 21 days intramuscularly (im) for 6 months, a total of 8 doses. At each study visit, octreotide was administered only after completion of all scheduled efficacy and safety evaluations for that visit. Octreotide was injected im into the right or left gluteal regions. The injections were

	initially administered by a trained and authorized member of the investigational team. When no study visit at the investigational site was required, the injections were given by a trained nurse or the family doctor.
Octreotide 60 mg Every 28 Days	Participants received octreotide 60 mg every 28 days intramuscularly (im) for 6 months, a total of 6 doses. Octreotide mg was administered as two 30 mg injections. At each study visit, octreotide was administered only after completion of all scheduled efficacy and safety evaluations for that visit. Octreotide was injected im into the right or left gluteal regions. The injections were initially administered by a trained and authorized member of the investigational team. When no study visit at the investigational site was required, the injections were given by a trained nurse or the family doctor.

Measured Values

	Octreotide 30 mg Every 21 Days	Octreotide 60 mg Every 28 Days
Number of Participants Analyzed [units: participants]	**15**	**11**
Percentage of Participants Asymptomatic for Acromegaly Symptoms at Week 12 and End of Study (Week 24) [units: Percentage of participants]		
Week 12	**33.3**	**9.09**
Week 24	**20.0**	**9.09**

No statistical analysis provided for Percentage of Participants Asymptomatic for Acromegaly Symptoms at Week 12 and End of Study (Week 24)

6. Secondary: Acromegaly Quality of Life (AcroQoL) Questionnaire Physical Scale Score at End of Study (Week 24) [Time Frame: End of study (Week 24)]

Measure Type	Secondary
Measure Title	Acromegaly Quality of Life (AcroQoL) Questionnaire Physical Scale Score at End of Study (Week 24)
Measure Description	The AcroQoL contains 8 items on Physical aspects. Participants were asked to rate each item on a 1-5 Likert scale measuring either the frequency of occurrence (always, most of the time, sometimes, rarely, or never) or the degree of

	agreement (completely agree, moderately agree, neither agree nor disagree, moderately disagree, completely disagree). The score on the physical scale can range from 8-40. A higher score indicates better Quality of Life.
Time Frame	End of study (Week 24)
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.
Intent-to-treat (ITT) population included all enrolled participants who received at least 1 dose of assigned study medication.

Reporting Groups

	Description
Octreotide 30 mg Every 21 Days	Participants received octreotide 30 mg every 21 days intramuscularly (im) for 6 months, a total of 8 doses. At each study visit, octreotide was administered only after completion of all scheduled efficacy and safety evaluations for that visit. Octreotide was injected im into the right or left gluteal regions. The injections were initially administered by a trained and authorized member of the investigational team. When no study visit at the investigational site was required, the injections were given by a trained nurse or the family doctor.
Octreotide 60 mg Every 28 Days	Participants received octreotide 60 mg every 28 days intramuscularly (im) for 6 months, a total of 6 doses. Octreotide mg was administered as two 30 mg injections. At each study visit, octreotide was administered only after completion of all scheduled efficacy and safety evaluations for that visit. Octreotide was injected im into the right or left gluteal regions. The injections were initially administered by a trained and authorized member of the investigational team. When no study visit at the investigational site was required, the injections were given by a trained nurse or the family doctor.

Measured Values

	Octreotide 30 mg Every 21 Days	Octreotide 60 mg Every 28 Days
Number of Participants Analyzed [units: participants]	**15**	**11**
Acromegaly Quality of Life (AcroQoL) Questionnaire Physical Scale Score at End		

of Study (Week 24) **[units: Percent of maximum score]** **Mean (Standard Deviation)**	**67.9 (22.6)**	**58.0 (21.8)**

No statistical analysis provided for Acromegaly Quality of Life (AcroQoL) Questionnaire Physical Scale Score at End of Study (Week 24)

7. Secondary: Acromegaly Quality of Life (AcroQoL) Questionnaire Psychological Scale Score at End of Study (Week 24) [Time Frame: End of study (Week 24)]

Measure Type	Secondary
Measure Title	Acromegaly Quality of Life (AcroQoL) Questionnaire Psychological Scale Score at End of Study (Week 24)
Measure Description	The AcroQoL contains 14 items on Psychological aspects. Participants were asked to rate each item on a 1-5 Likert scale measuring either the frequency of occurrence (always, most of the time, sometimes, rarely, or never) or the degree of agreement (completely agree, moderately agree, neither agree nor disagree, moderately disagree, completely disagree). The score on the psychological scale ranges from 14-70. A higher score indicates better Quality of Life.
Time Frame	End of study (Week 24)
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.
Intent-to-treat (ITT) population included all enrolled participants who received at least 1 dose of assigned study medication and who had data for this outcome measure.

Reporting Groups

	Description
Octreotide 30 mg Every 21 Days	Participants received octreotide 30 mg every 21 days intramuscularly (im) for 6 months, a total of 8 doses. At each study visit, octreotide was administered only after completion of all scheduled efficacy and safety

	evaluations for that visit. Octreotide was injected im into the right or left gluteal regions. The injections were initially administered by a trained and authorized member of the investigational team. When no study visit at the investigational site was required, the injections were given by a trained nurse or the family doctor.
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Measured Values

	Octreotide 30 mg Every 21 Days	Octreotide 60 mg Every 28 Days
Number of Participants Analyzed [units: participants]	**15**	**10**
Acromegaly Quality of Life (AcroQoL) Questionnaire Psychological Scale Score at End of Study (Week 24) [units: Percent of maximum score] Mean (Standard Deviation)	**65.1 (19.9)**	**72.1 (19.6)**

No statistical analysis provided for Acromegaly Quality of Life (AcroQoL) Questionnaire Psychological Scale Score at End of Study (Week 24)

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Octreotide 30 mg Every 21 Days	Participants received octreotide 30 mg every 21 days intramuscularly (im) for 6 months, a total of 8 doses. At each study visit, octreotide was administered only after completion of all scheduled efficacy and safety evaluations for that visit. Octreotide was injected im into the right or left gluteal regions. The injections were initially administered by a trained and authorized member of the investigational team. When no study visit at the investigational site was required, the injections were given by a trained nurse or the family doctor.
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Serious Adverse Events

	Octreotide 30 mg Every 21 Days	Octreotide 60 mg Every 28 Days
Total, serious adverse events		
# participants affected / at risk	**0/16 (0.00%)**	**0/12 (0.00%)**

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
Octreotide 30 mg Every 21 Days	Participants received octreotide 30 mg every 21 days intramuscularly (im) for 6 months, a total of 8 doses. At each study visit, octreotide was administered only after completion of all scheduled efficacy and safety evaluations for that visit. Octreotide was injected im into the right or left gluteal regions. The injections were initially administered by a trained and authorized member of the investigational team. When no study visit at the investigational site was required, the injections were given by a trained nurse or the family doctor.
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Other Adverse Events

	Octreotide 30 mg Every 21 Days	Octreotide 60 mg Every 28 Days
Total, other (not including serious) adverse events		
# participants affected / at risk	**3/16 (18.75%)**	**2/12 (16.67%)**
Gastrointestinal disorders		
Diarrhoea †		
# participants affected / at risk	**1/16 (6.25%)**	**2/12 (16.67%)**
# events	**1**	**2**
Flatulence †		
# participants affected / at risk	**2/16 (12.50%)**	**0/12 (0.00%)**
# events	**2**	**0**

† Events were collected by systematic assessment

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:

Mazziotti G, Porcelli T, Bogazzi F, Bugari G, Cannavò S, Colao A, Cozzi R, De Marinis L, degli Uberti E, Grottoli S, Minuto F, Montini M, Spinello M, Giustina A. Effects of high-dose octreotide LAR on glucose metabolism in patients with acromegaly inadequately controlled by conventional somatostatin analog therapy. Eur J Endocrinol. 2011 Mar;164(3):341-7. doi: 10.1530/EJE-10-0811. Epub 2011 Jan 6.

Responsible Party:	External Affairs, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00372697 History of Changes
Other Study ID Numbers:	**CSMS995BIT12**
Study First Received:	September 6, 2006
Results First Received:	January 12, 2011
Last Updated:	April 19, 2011
Health Authority:	Italy: Ethic Committee of Ospedali Civili di Brescia on behalf of National Health Authority