ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Trial record **1 of 1** for: CSMS995BIC03

Previous Study | Return to List | Next Study

Study to Evaluate the Efficacy and Safety of Sandostatin LAR at High Dose or in Combination Either With GH-receptor Antagonist or Dopamine-agonist in Acromegalic Patients (HOSCAR)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT01278342

First received: January 14, 2011
Last updated: April 20, 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 22, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Acromegaly
Interventions:	Drug: Sandostatin LAR Drug: pegvisomant Drug: cabergoline

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
Sandostatin LAR High Dose Alone	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with controlled GH and IGF-I after 3 months of Sandostatin LAR monotherapy continued to receive Sandostatin LAR 40 mg i.m. every 28 days for an additional 4 months.
Sandostatin LAR High Dose + Pegvisomat	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with uncontrolled GH and/or IGF-I, were randomized to receive Sandostatin LAR 40 mg every 28 days in combination with weekly doses of Pegvisomant 70 mg subcutaneously (s.c.) for a further 4 months.
Sandostatin LAR High Dose + Cabergoline	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with uncontrolled GH and/or IGF-I, were randomized to receive Sandostatin LAR 40 mg every 28 days in combination with weekly doses of Cabergoline for a further 4 months, with Cabergoline doses as follows: • 1st week: 0.25 mg twice a week (0.50 mg/week) • 2nd week: 0.50 mg/week twice a week (1 mg/week) • 3rd week: 0.50 mg four times a week (2 mg/week) • 4th week: 0.50 mg daily (3.5 mg/week) Subsequent 3 months: 0.50 mg daily (3.5 mg/week)

Participant Flow: Overall Study

	Sandostatin LAR High Dose Alone	Sandostatin LAR High Dose + Pegvisomat	Sandostatin LAR High Dose + Cabergoline
STARTED	7	31	32
COMPLETED	3	30	32
NOT COMPLETED	4	1	0
Physician Decision	0	1	0
Lost to Follow-up	1	0	0
Administrative problems	2	0	0
Other	1	0	0

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
Sandostatin LAR High Dose Alone	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with controlled GH and IGF-I after 3 months of Sandostatin LAR monotherapy continued to receive Sandostatin LAR 40 mg i.m. every 28 days for an additional 4 months.

Sandostatin LAR High Dose + Pegvisomat	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with uncontrolled GH and/or IGF-I, were randomized to receive Sandostatin LAR 40 mg every 28 days in combination with weekly doses of Pegvisomant 70 mg subcutaneously (s.c.) for a further 4 months.
Sandostatin LAR High Dose + Cabergoline	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with uncontrolled GH and/or IGF-I, were randomized to receive Sandostatin LAR 40 mg every 28 days in combination with weekly doses of Cabergoline for a further 4 months, with Cabergoline doses as follows: • 1st week: 0.25 mg twice a week (0.50 mg/week) • 2nd week: 0.50 mg/week twice a week (1 mg/week) • 3rd week: 0.50 mg four times a week (2 mg/week) • 4th week: 0.50 mg daily (3.5 mg/week) Subsequent 3 months: 0.50 mg daily (3.5 mg/week)
Total	Total of all reporting groups

Baseline Measures

	Sandostatin LAR High Dose Alone	Sandostatin LAR High Dose + Pegvisomat	Sandostatin LAR High Dose + Cabergoline	Total
Number of Participants [units: participants]	**7**	**31**	**32**	**70**
Age [units: years] Mean (Standard Deviation)	**57.9 (7.71)**	**44.6 (10.54)**	**49.3 (10.50)**	**48.1 (10.90)**
Gender [units: participants]				
Female	**3**	**17**	**18**	**38**
Male	**4**	**14**	**14**	**32**

Outcome Measures

Hide All Outcome Measures

1. Primary: The Percentage of Participants With Complete Response (CR) at 8 Months [Time Frame: From Baseline to 8 months]

Measure Type	Primary
Measure Title	The Percentage of Participants With Complete Response (CR) at 8 Months
Measure Description	A patient was classified as a Complete Responder (CR) if both biochemical parameters were controlled at the end of 8 months of treatment: • Mean 1 hour GH < 2.5µg/L (according to Central Laboratory); and • IGF-I within the Central Laboratory Normal Range (for age and gender).
Time Frame	From Baseline to 8 months
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 population - all participants receiving at least one dose of Sandostatin LAR

Reporting Groups

	Description
Sandostatin LAR High Dose Alone	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with controlled GH and IGF-I after 3 months of Sandostatin LAR monotherapy continued to receive Sandostatin LAR 40 mg i.m. every 28 days for an additional 4 months.
Sandostatin LAR High Dose + Pegvisomat	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with uncontrolled GH and/or IGF-I, were randomized to receive Sandostatin LAR 40 mg every 28 days in combination with weekly doses of Pegvisomant

	70 mg subcutaneously (s.c.) for a further 4 months.
Sandostatin LAR High Dose + Cabergoline	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with uncontrolled GH and/or IGF-I, were randomized to receive Sandostatin LAR 40 mg every 28 days in combination with weekly doses of Cabergoline for a further 4 months, with Cabergoline doses as follows: • 1st week: 0.25 mg twice a week (0.50 mg/week) • 2nd week: 0.50 mg/week twice a week (1 mg/week) • 3rd week: 0.50 mg four times a week (2 mg/week) • 4th week: 0.50 mg daily (3.5 mg/week) Subsequent 3 months: 0.50 mg daily (3.5 mg/week)

Measured Values

	Sandostatin LAR High Dose Alone	Sandostatin LAR High Dose + Pegvisomat	Sandostatin LAR High Dose + Cabergoline
Number of Participants Analyzed [units: participants]	**7**	**31**	**32**
The Percentage of Participants With Complete Response (CR) at 8 Months [units: percent] Number (95% Confidence Interval)			
% Participants with Complete Response	**25 (0.6 to 80.6)**	**0 (0 to 11.2)**	**9.4 (2.0 to 25.0)**

No statistical analysis provided for The Percentage of Participants With Complete Response (CR) at 8 Months

2. Secondary: The Percentage of Participants With Complete Response (CR) At 3 Months [Time Frame: From Baseline to 3 months]

Measure Type	Secondary
Measure Title	The Percentage of Participants With Complete Response (CR) At 3 Months

Measure Description	A patient was classified as CR if both biochemical parameters were controlled at the end of 3 months of treatment: • Mean 1 hour GH < 2.5µg/L (according to Central Laboratory); and • IGF-I within the Central Laboratory Normal Range (for age and gender)
Time Frame	From Baseline to 3 months
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 population - all participants receiving at least one dose of Sandostatin LAR

Reporting Groups

	Description
Sandostatin LAR High Dose Alone	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with controlled GH and IGF-I after 3 months of Sandostatin LAR monotherapy continued to receive Sandostatin LAR 40 mg i.m. every 28 days for an additional 4 months.
Sandostatin LAR High Dose + Pegvisomat	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with uncontrolled GH and/or IGF-I, were randomized to receive Sandostatin LAR 40 mg every 28 days in combination with weekly doses of Pegvisomant 70 mg subcutaneously (s.c.) for a further 4 months.
Sandostatin LAR High Dose + Cabergoline	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with uncontrolled GH and/or IGF-I, were randomized to receive Sandostatin LAR 40 mg every 28 days in combination with weekly doses of Cabergoline for a further 4 months, with Cabergoline doses as follows: • 1st week: 0.25 mg twice a week (0.50 mg/week) • 2nd week: 0.50 mg/week twice a week (1 mg/week) • 3rd week: 0.50 mg four times a week (2 mg/week) • 4th week: 0.50 mg daily (3.5 mg/week) Subsequent 3 months: 0.50 mg daily (3.5 mg/week)

Measured Values

	Sandostatin LAR High Dose Alone	Sandostatin LAR High Dose + Pegvisomat	Sandostatin LAR High Dose + Cabergoline
Number of Participants Analyzed [units: participants]	**7**	**31**	**32**
The Percentage of Participants With Complete Response (CR) At 3 Months [units: percent] Number (95% Confidence Interval)			
% Participants with Complete Response	**60 (14.7 to 94.7)**	**0 (0 to 11.2)**	**0 (0 to 10.9)**

No statistical analysis provided for The Percentage of Participants With Complete Response (CR) At 3 Months

3. Secondary: The Percentage of Participants With Partial Response (PR) at 8 Months [Time Frame: From Baseline to 8 months]

Measure Type	Secondary
Measure Title	The Percentage of Participants With Partial Response (PR) at 8 Months
Measure Description	Patients who met one of the following criteria at the end of 8 months of treatment were defined as Partial Responders, regardless of the treatment. • Mean 1 hour GH > 2.5 µg/L and < 5 µg/L and either a decrease in IGF-I of at least 50% compared to baseline or IGF-I within normal range. • Mean 1 hour GH < 2.5 µg/L and a decrease in IGF-I of at least 50% compared to baseline and IGF-I outside normal range.
Time Frame	From Baseline to 8 months
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 population - all participants receiving at least one dose of Sandostatin LAR

Reporting Groups

	Description
Sandostatin LAR High Dose Alone	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with controlled GH and IGF-I after 3 months of Sandostatin LAR monotherapy continued to receive Sandostatin LAR 40 mg i.m. every 28 days for an additional 4 months.
Sandostatin LAR High Dose + Pegvisomat	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with uncontrolled GH and/or IGF-I, were randomized to receive Sandostatin LAR 40 mg every 28 days in combination with weekly doses of Pegvisomant 70 mg subcutaneously (s.c.) for a further 4 months.
Sandostatin LAR High Dose + Cabergoline	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with uncontrolled GH and/or IGF-I, were randomized to receive Sandostatin LAR 40 mg every 28 days in combination with weekly doses of Cabergoline for a further 4 months, with Cabergoline doses as follows: • 1st week: 0.25 mg twice a week (0.50 mg/week) • 2nd week: 0.50 mg/week twice a week (1 mg/week) • 3rd week: 0.50 mg four times a week (2 mg/week) • 4th week: 0.50 mg daily (3.5 mg/week) Subsequent 3 months: 0.50 mg daily (3.5 mg/week)

Measured Values

	Sandostatin LAR High Dose Alone	**Sandostatin LAR High Dose + Pegvisomat**	**Sandostatin LAR High Dose + Cabergoline**
Number of Participants Analyzed [units: participants]	**7**	**31**	**32**
The Percentage of Participants With Partial			

Response (PR) at 8 Months [units: percent] Number (95% Confidence Interval)			
% participants with Partial Response	**25 (0.6 to 80.6)**	**22.6 (9.6 to 41.1)**	**21.9 (9.3 to 40.0)**

No statistical analysis provided for The Percentage of Participants With Partial Response (PR) at 8 Months

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Sandostatin LAR High Dose Alone	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with controlled GH and IGF-I after 3 months of Sandostatin LAR monotherapy continued to receive Sandostatin LAR 40 mg i.m. every 28 days for an additional 4 months
Sandostatin LAR High Dose + Pegvisomant	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with uncontrolled GH and/or IGF-I, were randomized to receive Sandostatin LAR 40 mg every 28 days in combination with weekly doses of Pegvisomant 70 mg subcutaneously (s.c.) for a further 4 months.
Sandostatin LAR High Dose + Cabergoline	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with uncontrolled GH and/or IGF-I, were randomized to receive Sandostatin LAR 40 mg every 28 days in combination with weekly doses of Cabergoline for a further 4 months, with Cabergoline doses as follows: • 1st week: 0.25 mg twice a week (0.50 mg/week)

	• 2nd week: 0.50 mg/week twice a week (1 mg/week) • 3rd week: 0.50 mg four times a week (2 mg/week) • 4th week: 0.50 mg daily (3.5 mg/week) Subsequent 3 months: 0.50 mg daily (3.5 mg/week)

Serious Adverse Events

	Sandostatin LAR High Dose Alone	Sandostatin LAR High Dose + Pegvisomant	Sandostatin LAR High Dose + Cabergoline
Total, serious adverse events			
# participants affected / at risk	**0/7 (0.00%)**	**1/32 (3.13%)**	**2/31 (6.45%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Renal cell carcinoma † 1			
# participants affected / at risk	**0/7 (0.00%)**	**0/32 (0.00%)**	**1/31 (3.23%)**
Nervous system disorders			
IIIrd nerve paralysis † 1			
# participants affected / at risk	**0/7 (0.00%)**	**0/32 (0.00%)**	**1/31 (3.23%)**
Vascular disorders			
Deep vein thrombosis † 1			
# participants affected / at risk	**0/7 (0.00%)**	**1/32 (3.13%)**	**0/31 (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
Sandostatin LAR High Dose Alone	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with controlled GH and IGF-I after 3 months of Sandostatin LAR monotherapy continued to receive Sandostatin LAR 40 mg i.m. every 28 days for an additional 4 months
Sandostatin LAR High Dose + Pegvisomant	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with uncontrolled GH and/or IGF-I, were randomized to receive Sandostatin LAR 40 mg every 28 days in combination with weekly doses of Pegvisomant 70 mg subcutaneously (s.c.) for a further 4 months.
Sandostatin LAR High Dose + Cabergoline	All patients were treated with Sandostatin LAR 40 mg i.m. every 28 days for 3 months. Following biochemical assessment, patients with uncontrolled GH and/or IGF-I, were randomized to receive Sandostatin LAR 40 mg every 28 days in combination with weekly doses of Cabergoline for a further 4 months, with Cabergoline doses as follows: • 1st week: 0.25 mg twice a week (0.50 mg/week) • 2nd week: 0.50 mg/week twice a week (1 mg/week) • 3rd week: 0.50 mg four times a week (2 mg/week) • 4th week: 0.50 mg daily (3.5 mg/week) Subsequent 3 months: 0.50 mg daily (3.5 mg/week)

Other Adverse Events

	Sandostatin LAR High Dose Alone	**Sandostatin LAR High Dose + Pegvisomant**	**Sandostatin LAR High Dose + Cabergoline**
Total, other (not including serious) adverse events			

# participants affected / at risk	4/7 (57.14%)	15/32 (46.88%)	12/31 (38.71%)
Ear and labyrinth disorders			
Vertigo † 1			
# participants affected / at risk	0/7 (0.00%)	1/32 (3.13%)	2/31 (6.45%)
Gastrointestinal disorders			
Abdominal pain † 1			
# participants affected / at risk	0/7 (0.00%)	2/32 (6.25%)	3/31 (9.68%)
Diarrhoea † 1			
# participants affected / at risk	0/7 (0.00%)	4/32 (12.50%)	3/31 (9.68%)
Dyspepsia † 1			
# participants affected / at risk	0/7 (0.00%)	2/32 (6.25%)	0/31 (0.00%)
Flatulence † 1			
# participants affected / at risk	0/7 (0.00%)	2/32 (6.25%)	0/31 (0.00%)
Infections and infestations			
Nasopharyngitis † 1			
# participants affected / at risk	1/7 (14.29%)	2/32 (6.25%)	1/31 (3.23%)
Pneumonia † 1			
# participants affected / at risk	1/7 (14.29%)	0/32 (0.00%)	0/31 (0.00%)
Investigations			
Blood glucose increased † 1			
# participants affected / at risk	0/7 (0.00%)	4/32 (12.50%)	0/31 (0.00%)
Blood insulin decreased † 1			
# participants affected / at risk	1/7 (14.29%)	0/32 (0.00%)	0/31 (0.00%)
Glycosylated haemoglobin increased † 1			

# participants affected / at risk	**0/7 (0.00%)**	**2/32 (6.25%)**	**0/31 (0.00%)**
Metabolism and nutrition disorders			
Diabetes mellitus † 1			
# participants affected / at risk	**0/7 (0.00%)**	**2/32 (6.25%)**	**1/31 (3.23%)**
Musculoskeletal and connective tissue disorders			
Arthralgia † 1			
# participants affected / at risk	**0/7 (0.00%)**	**0/32 (0.00%)**	**3/31 (9.68%)**
Back pain † 1			
# participants affected / at risk	**0/7 (0.00%)**	**1/32 (3.13%)**	**3/31 (9.68%)**
Nervous system disorders			
Aphonia † 1			
# participants affected / at risk	**1/7 (14.29%)**	**0/32 (0.00%)**	**0/31 (0.00%)**
Headache † 1			
# participants affected / at risk	**0/7 (0.00%)**	**0/32 (0.00%)**	**4/31 (12.90%)**
Renal and urinary disorders			
Calculus bladder † 1			
# participants affected / at risk	**1/7 (14.29%)**	**0/32 (0.00%)**	**0/31 (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 (i.e., 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

Responsible Party:	External Affairs, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT01278342 History of Changes
Other Study ID Numbers:	**CSMS995BIC03** 2005-005852-42 (Registry Identifier: EudraCT)
Study First Received:	January 14, 2011
Results First Received:	January 22, 2011
Last Updated:	April 20, 2011
Health Authority:	France: National Consultative Ethics Committee for Health and Life Sciences Italy: National Monitoring Centre for Clinical Trials - Ministry of Health Portugal: Health Ethic Committee Switzerland: Swissmedic Poland: Ministry of Health