ClinicalTrials.gov

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

Trial record **1 of 1** for: CICL670A2417

Previous Study | Return to List | Next Study

Myelodysplastic Syndrome (MDS) Gastrointestinal (GI) Tolerability Study (MACS1574)

This study has been terminated.

(The trial was terminated due to insufficient enrollment.)

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01326845

First received: March 30, 2011
Last updated: September 11, 2013
Last verified: September 2013
History of Changes

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

Results First Received: September 11, 2013

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Myelodysplastic Syndrome, Transfusional Iron Overload
Intervention:	Drug: Deferasirox

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
Deferasirox am	Deferasirox 20 mg/kg/day taken in the morning, 30 minutes before food
Deferasirox pm	Deferasirox 20 mg/kg/day taken in the evening, no less than 2 hours after the last food intake or at least 30 minutes before the evening meal

Participant Flow: Overall Study

	Deferasirox am	Deferasirox pm
STARTED	**7**	**5**
COMPLETED	**0** [1]	**0** [1]
NOT COMPLETED	**7**	**5**
Administrative Problems	**5**	**2**
Adverse Event	**1**	**0**
Misisng	**1**	**3**

[1] Study terminated early

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
Deferasirox am	Deferasirox 20 mg/kg/day taken in the morning, 30 minutes before food
Deferasirox pm	Deferasirox 20 mg/kg/day taken in the evening, no less than 2 hours after the last food intake or at least 30 minutes before the evening meal
Total	Total of all reporting groups

Baseline Measures

	Deferasirox am	**Deferasirox pm**	**Total**
Number of Participants [units: participants]	**7**	**5**	**12**
Age [units: Years] Mean (Standard Deviation)	**69.7 (7.5)**	**71.6 (8.65)**	**70.5 (7.67)**
Gender [units: Participants]			
Female	**3**	**3**	**6**
Male	**4**	**2**	**6**

Outcome Measures

Hide All Outcome Measures

1. Primary: Difference in the Frequency of Overall Newly Occurring GI Adverse Events (AEs) in the Two Treatment Arms [Time Frame: 3 months]

Measure Type	Primary
Measure Title	Difference in the Frequency of Overall Newly Occurring GI Adverse Events (AEs) in the Two Treatment Arms
Measure Description	Study was prematurely terminated and not powered for efficacy. Frequency of GI AEs during the overall study period is available in the AE tables reported in the safety section.
Time Frame	3 months
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.
No text entered.

Reporting Groups

	Description
Deferasirox am	Deferasirox 20 mg/kg/day taken in the morning, 30 minutes before food
Deferasirox pm	Deferasirox 20 mg/kg/day taken in the evening, no less than 2 hours after the last food intake or at least 30 minutes before the evening meal

Measured Values

	Deferasirox am	**Deferasirox pm**
Number of Participants Analyzed [units: participants]	**0**	**0**
Difference in the Frequency of Overall Newly Occurring GI Adverse Events (AEs) in the Two Treatment Arms		

No statistical analysis provided for Difference in the Frequency of Overall Newly Occurring GI Adverse Events (AEs) in the Two Treatment Arms

2. Secondary: Difference in Frequency of Overall Newly Occurring GI AEs Between the Two Treatment Groups at Month 6. [Time Frame: 6 months]

Measure Type	Secondary
Measure Title	Difference in Frequency of Overall Newly Occurring GI AEs Between the Two Treatment Groups at Month 6.
Measure Description	Study was prematurely terminated and not powered for efficacy.
Time Frame	6 months
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.
No text entered.

Reporting Groups

	Description
Deferasirox am	Deferasirox 20 mg/kg/day taken in the morning, 30 minutes before food
Deferasirox pm	Deferasirox 20 mg/kg/day taken in the evening, no less than 2 hours after the last food intake or at least 30 minutes before the evening meal

Measured Values

	Deferasirox am	**Deferasirox pm**
Number of Participants Analyzed [units: participants]	**0**	**0**
Difference in Frequency of Overall Newly Occurring GI AEs Between the Two Treatment Groups at Month 6.		

No statistical analysis provided for Difference in Frequency of Overall Newly Occurring GI AEs Between the Two Treatment Groups at Month 6.

3. Secondary: Difference in Frequency of Specific Commonly Reported GI AEs Between the Two Treatment Groups [Time Frame: months 3 and 6.]

Measure Type	Secondary
Measure Title	Difference in Frequency of Specific Commonly Reported GI AEs Between the Two Treatment Groups
Measure Description	Study was prematurely terminated and not powered for efficacy.
Time Frame	months 3 and 6.
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.
No text entered.

Reporting Groups

	Description
Deferasirox am	Deferasirox 20 mg/kg/day taken in the morning, 30 minutes before food
Deferasirox pm	Deferasirox 20 mg/kg/day taken in the evening, no less than 2 hours after the last food intake or at least 30 minutes before the evening meal

Measured Values

	Deferasirox am	**Deferasirox pm**
Number of Participants Analyzed [units: participants]	**0**	**0**
Difference in Frequency of Specific Commonly Reported GI AEs Between the Two Treatment Groups		

No statistical analysis provided for Difference in Frequency of Specific Commonly Reported GI AEs Between the Two Treatment Groups

4. Secondary: Difference in Severity of Overall GI AEs Between the Two Treatment Groups [Time Frame: months 3 and 6.]

Measure Type	Secondary
Measure Title	Difference in Severity of Overall GI AEs Between the Two Treatment Groups
Measure Description	Study was prematurely terminated and not powered for efficacy.
Time Frame	months 3 and 6.
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.
No text entered.

Reporting Groups

	Description
Deferasirox am	Deferasirox 20 mg/kg/day taken in the morning, 30 minutes before food
Deferasirox pm	Deferasirox 20 mg/kg/day taken in the evening, no less than 2 hours after the last food intake or at least 30 minutes before the evening meal

Measured Values

	Deferasirox am	**Deferasirox pm**
Number of Participants Analyzed [units: participants]	**0**	**0**
Difference in Severity of Overall GI AEs Between the Two Treatment Groups		

No statistical analysis provided for Difference in Severity of Overall GI AEs Between the Two Treatment Groups

5. Secondary: Difference in Severity of Specific Commonly Reported GI Symptoms Between the Two Treatment Groups [Time Frame: months 3 and 6]

Measure Type	Secondary
Measure Title	Difference in Severity of Specific Commonly Reported GI Symptoms Between the Two Treatment Groups
Measure Description	Study was prematurely terminated and not powered for efficacy.
Time Frame	months 3 and 6
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.
No text entered.

Reporting Groups

	Description
Deferasirox am	Deferasirox 20 mg/kg/day taken in the morning, 30 minutes before food
Deferasirox pm	Deferasirox 20 mg/kg/day taken in the evening, no less than 2 hours after the last food intake or at least 30 minutes before the evening meal

Measured Values

	Deferasirox am	**Deferasirox pm**
Number of Participants Analyzed [units: participants]	**0**	**0**
Difference in Severity of Specific Commonly Reported GI Symptoms Between the Two Treatment Groups		

No statistical analysis provided for Difference in Severity of Specific Commonly Reported GI Symptoms Between the Two Treatment Groups

6. Secondary: Difference in Frequency and Severity of All Non-GI AEs Between the Two Treatment Groups [Time Frame: months 3 and 6]

Measure Type	Secondary
Measure Title	Difference in Frequency and Severity of All Non-GI AEs Between the Two Treatment Groups
Measure Description	Study was prematurely terminated and not powered for efficacy.
Time Frame	months 3 and 6
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.
No text entered.

Reporting Groups

	Description
Deferasirox am	Deferasirox 20 mg/kg/day taken in the morning, 30 minutes before food
Deferasirox pm	Deferasirox 20 mg/kg/day taken in the evening, no less than 2 hours after the last food intake or at least 30 minutes before the evening meal

Measured Values

	Deferasirox am	**Deferasirox pm**
Number of Participants Analyzed [units: participants]	**0**	**0**
Difference in Frequency and Severity of All Non-GI AEs Between the Two Treatment Groups		

No statistical analysis provided for Difference in Frequency and Severity of All Non-GI AEs Between the Two Treatment Groups

7. Secondary: the Difference Between the Time From Baseline to the First Occurrence of GI AEs Between the Two Treatment Groups [Time Frame: 3 months, 6 months]

Measure Type	Secondary
Measure Title	the Difference Between the Time From Baseline to the First Occurrence of GI AEs Between the Two Treatment Groups
Measure Description	Study was prematurely terminated and not powered for efficacy.
Time Frame	3 months, 6 months
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.
No text entered.

Reporting Groups

	Description
Deferasirox am	Deferasirox 20 mg/kg/day taken in the morning, 30 minutes before food
Deferasirox pm	Deferasirox 20 mg/kg/day taken in the evening, no less than 2 hours after the last food intake or at least 30 minutes before the evening meal

Measured Values

	Deferasirox am	**Deferasirox pm**
Number of Participants Analyzed [units: participants]	**0**	**0**
the Difference Between the Time From Baseline to the First Occurrence of GI AEs Between the Two Treatment Groups		

No statistical analysis provided for the Difference Between the Time From Baseline to the First Occurrence of GI AEs Between the Two Treatment Groups

8. Secondary: Difference in Severity of GI Symptoms, Bowel Habits and Level of Satisfaction From the Patient's Perspective Between the Two Treatment Groups [Time Frame: 3 months, 6 months]

Measure Type	Secondary
Measure Title	Difference in Severity of GI Symptoms, Bowel Habits and Level of Satisfaction From the Patient's Perspective Between the Two Treatment Groups
Measure Description	No text entered.
Time Frame	3 months, 6 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.
No text entered.

Reporting Groups

	Description
Deferasirox am	Deferasirox 20 mg/kg/day taken in the morning, 30 minutes before food
Deferasirox pm	Deferasirox 20 mg/kg/day taken in the evening, no less than 2 hours after the last food intake or at least 30 minutes before the evening meal

Measured Values

	Deferasirox am	**Deferasirox pm**
Number of Participants Analyzed [units: participants]	**0**	**0**
Difference in Severity of GI Symptoms, Bowel Habits and Level of Satisfaction From the Patient's Perspective Between		

the Two Treatment Groups		

No statistical analysis provided for Difference in Severity of GI Symptoms, Bowel Habits and Level of Satisfaction From the Patient's Perspective Between the Two Treatment Groups

9. Secondary: Difference in Reducing Serum Ferritin After Each Month of Study Drug Administration Between the Two Groups [Time Frame: 3 months, 6 months]

Measure Type	Secondary
Measure Title	Difference in Reducing Serum Ferritin After Each Month of Study Drug Administration Between the Two Groups
Measure Description	Study was prematurely terminated and not powered for efficacy.
Time Frame	3 months, 6 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.
No text entered.

Reporting Groups

	Description
Deferasirox am	Deferasirox 20 mg/kg/day taken in the morning, 30 minutes before food
Deferasirox pm	Deferasirox 20 mg/kg/day taken in the evening, no less than 2 hours after the last food intake or at least 30 minutes before the evening meal

Measured Values

	Deferasirox am	**Deferasirox pm**
Number of Participants Analyzed		

[units: participants]	**0**	**0**
Difference in Reducing Serum Ferritin After Each Month of Study Drug Administration Between the Two Groups		

No statistical analysis provided for Difference in Reducing Serum Ferritin After Each Month of Study Drug Administration Between the Two Groups

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	6 months
Additional Description	No text entered.

Reporting Groups

	Description
ICL am	ICL am
ICL pm	ICL pm

Serious Adverse Events

	ICL am	ICL pm
Total, serious adverse events		
# participants affected / at risk	**1/7 (14.29%)**	**2/5 (40.00%)**
Blood and lymphatic system disorders		
Anaemia †1		
# participants affected / at risk	**0/7 (0.00%)**	**1/5 (20.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Leukaemia †1		
# participants affected / at risk	**1/7 (14.29%)**	**0/5 (0.00%)**

Vascular disorders		
Jugular vein thrombosis †1		
# participants affected / at risk	**0/7 (0.00%)**	**1/5 (20.00%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	6 months
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
ICL am	ICL am
ICL pm	ICL pm

Other Adverse Events

	ICL am	ICL pm
Total, other (not including serious) adverse events		
# participants affected / at risk	**5/7 (71.43%)**	**2/5 (40.00%)**
Blood and lymphatic system disorders		
Anaemia †1		
# participants affected / at risk	**2/7 (28.57%)**	**0/5 (0.00%)**

Neutropenia [†1]		
# participants affected / at risk	0/7 (0.00%)	1/5 (20.00%)
Gastrointestinal disorders		
Abdominal pain upper [†1]		
# participants affected / at risk	0/7 (0.00%)	1/5 (20.00%)
Diarrhoea [†1]		
# participants affected / at risk	1/7 (14.29%)	0/5 (0.00%)
Gastrointestinal disorder [†1]		
# participants affected / at risk	1/7 (14.29%)	0/5 (0.00%)
Nausea [†1]		
# participants affected / at risk	2/7 (28.57%)	0/5 (0.00%)
Vomiting [†1]		
# participants affected / at risk	1/7 (14.29%)	0/5 (0.00%)
General disorders		
Asthenia [†1]		
# participants affected / at risk	2/7 (28.57%)	1/5 (20.00%)
Oedema peripheral [†1]		
# participants affected / at risk	2/7 (28.57%)	0/5 (0.00%)
Infections and infestations		
Lyme disease [†1]		
# participants affected / at risk	1/7 (14.29%)	0/5 (0.00%)
Staphylococcal infection [†1]		
# participants affected / at risk	0/7 (0.00%)	1/5 (20.00%)
Upper respiratory tract infection [†1]		
# participants affected / at risk	1/7 (14.29%)	0/5 (0.00%)
Investigations		
Alanine aminotransferase increased [†1]		
# participants affected / at risk	1/7 (14.29%)	0/5 (0.00%)

Aspartate aminotransferase increased †1		
# participants affected / at risk	**1/7 (14.29%)**	**0/5 (0.00%)**
Blood alkaline phosphatase increased †1		
# participants affected / at risk	**1/7 (14.29%)**	**0/5 (0.00%)**
Blood creatinine increased †1		
# participants affected / at risk	**1/7 (14.29%)**	**0/5 (0.00%)**
Gamma-glutamyltransferase increased †1		
# participants affected / at risk	**1/7 (14.29%)**	**0/5 (0.00%)**
Metabolism and nutrition disorders		
Decreased appetite †1		
# participants affected / at risk	**1/7 (14.29%)**	**0/5 (0.00%)**
Musculoskeletal and connective tissue disorders		
Pain in extremity †1		
# participants affected / at risk	**0/7 (0.00%)**	**1/5 (20.00%)**
Renal and urinary disorders		
Renal impairment †1		
# participants affected / at risk	**1/7 (14.29%)**	**0/5 (0.00%)**
Skin and subcutaneous tissue disorders		
Rash †1		
# participants affected / at risk	**1/7 (14.29%)**	**0/5 (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:**
Principal Investigators are NOT employed by the organization sponsoring the study. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

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 pooled data (i.e.,data from all sites) in clinical trial.

Results Point of Contact:

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

No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT01326845 History of Changes
Other Study ID Numbers:	**CICL670A2417** 2011-001077-13 (EudraCT Number)
Study First Received:	March 30, 2011
Results First Received:	September 11, 2013
Last Updated:	September 11, 2013
Health Authority:	United States: Food and Drug Administration France: Agence française de sécurité sanitaire des produits de santé Germany: Bundesinstitut für Arzneimittel und Medizinprodukte Hungary: National Institute of Pharmacy Spain: Agencie Española de Medicamentos y Productos Sanitarios