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Trial record **1 of 1** for: CICL670A0109E1

Previous Study | Return to List | Next Study

Evaluation of the Safety, Tolerability, Pharmacokinetics (PK) and Effects on Liver Iron Concentration of ICL670 Relative to Deferoxamine(DFO).

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT01090323

First received: March 15, 2010
Last updated: May 3, 2011
Last verified: May 2011
History of Changes

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

Results First Received: December 21, 2010

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Sickle Cell Disease
Intervention:	Drug: ICL670

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
ICL670	Participants treated with ICL670 during the Core Study 0109(NCT00067080) and during the extension phase. ICL670 was administered orally once a day based on the participant's body weight.
Crossover	Participants treated with Deferoxamine (DFO) during the Core Study 0109 (NCT00067080) and treated with ICL670 during the extension phase. ICL670 was administered orally once a day based on the participant's body weight.

Participant Flow: Overall Study

	ICL670	Crossover
STARTED	132	53
COMPLETED	43	19
NOT COMPLETED	89	34
Adverse Event	12	2
Abnormal Lab Values	3	1
Abnormal Test Procedure Results	2	0
Unsatisfactory therapeutic effect	4	2
Condition no longer requires drug	5	4

Protocol Violation	**2**	**1**
Withdrew consent	**33**	**11**
Lost to Follow-up	**11**	**6**
Administrative problems	**6**	**4**
Death	**1**	**2**
Stopped end of core	**7**	**0**
Stopped end of extension 1#	**3**	**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
ICL670	Participants treated with ICL670 during the Core Study 0109(NCT00067080) and during the extension phase. ICL670 was administered orally once a day based on the participant's body weight.
Crossover	Participants treated with Deferoxamine (DFO) during the Core Study 0109 (NCT00067080) and treated with ICL670 during the extension phase. ICL670 was administered orally once a day based on the participant's body weight.
Total	Total of all reporting groups

Baseline Measures

	ICL670	Crossover	Total
Number of Participants [units: participants]	**132**	**53**	**185**
Age, Customized [units: participants]			
<12 years	**33**	**14**	**47**
12 - <16 years	**32**	**11**	**43**
16 - <65 years	**67**	**28**	**95**
Gender [units: participants]			
Female	**80**	**31**	**111**
Male	**52**	**22**	**74**
Region of Enrollment [units: participants]			
France	**10**	**2**	**12**
United States	**110**	**46**	**156**
Canada	**0**	**1**	**1**
United Kingdom	**5**	**1**	**6**
Italy	**7**	**3**	**10**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With Adverse Events After Start of ICL670 [Time Frame: 0 - 60 months]

Measure Type	Primary
Measure Title	Number of Participants With Adverse Events After Start of ICL670
Measure Description	Safety as assessed by the number of participants with adverse event or death after the start of ICL670.
Time Frame	0 - 60 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.
The primary analysis was on Safety Analysis Set which comprised all participants who received at least one dose of ICL670 during the core/extension phase of the study. All participants previously treated with ICL670/DFO for 52weeks in the core study.

Reporting Groups

	Description
ICL670	Participants treated with ICL670 during the Core Study 0109(NCT00067080) and during the extension phase. ICL670 was administered orally once a day based on the participant's body weight.
Crossover	Participants treated with Deferoxamine (DFO) during the Core Study 0109 (NCT00067080) and treated with ICL670 during the extension phase. ICL670 was administered orally once a day based on the participant's body weight.

Measured Values

	ICL670	Crossover
Number of Participants Analyzed [units: participants]	**132**	**53**
Number of Participants With Adverse Events After Start of ICL670 [units: participants]		
Adverse Events	**131**	**49**
Deaths	**1**	**2**

No statistical analysis provided for Number of Participants With Adverse Events After Start of ICL670

2. Secondary: Change in Serum Ferritin From Start of ICL670 to End of Study [Time Frame: 0 - 60 months]

Measure Type	Secondary
Measure Title	Change in Serum Ferritin From Start of ICL670 to End of Study
Measure Description	The main efficacy variable was change in serum ferritin in response to therapy with ICL670. Due to variability of serum ferritin, end of study was considered as the mean of at most the last 3 available observations after the start of ICL670.
Time Frame	0 - 60 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.
The primary analysis was on Full Analysis Set which comprised all participants who received at least one dose of ICL670 during the core or the extension phase of the study. All participants previously treated with ICL670 or DFO for 52 weeks in the core study were eligible for enrollment.

Reporting Groups

	Description
ICL670	Participants treated with ICL670 during the Core Study 0109(NCT00067080) and during the extension phase. ICL670 was administered orally once a day based on the participant's body weight.
Crossover	Participants treated with Deferoxamine (DFO) during the Core Study 0109 (NCT00067080) and treated with ICL670 during the extension phase. ICL670 was administered orally once a day based on the participant's body weight.

Measured Values

	ICL670	Crossover
Number of Participants Analyzed [units: participants]	**132**	**53**
Change in Serum Ferritin From Start of ICL670 to End of Study [units: µg/L] Median (Full Range)	**-245.5 (-8701.3 to 7626.5)**	**-134.3 (-6124.0 to 5136.7)**

No statistical analysis provided for Change in Serum Ferritin From Start of ICL670 to End of Study

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
ICL670	Participants treated with ICL670 during the Core Study 0109(NCT00067080) and during the extension phase. ICL670 was administered orally once a day based on the participant's body weight.
Crossover	Participants treated with Deferoxamine (DFO) during the Core Study 0109 (NCT00067080) and treated with ICL670 during the extension phase. ICL670 was administered orally once a day based on the participant's body weight.

Serious Adverse Events

	ICL670	Crossover
Total, serious adverse events		
# participants affected / at risk	**97/132 (73.48%)**	**34/53 (64.15%)**

Blood and lymphatic system disorders		
Acute chest syndrome † 1		
# participants affected / at risk	**5/132 (3.79%)**	**3/53 (5.66%)**
Anaemia † 1		
# participants affected / at risk	**1/132 (0.76%)**	**2/53 (3.77%)**
Anaemia haemolytic autoimmune † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Coagulopathy † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Haemolysis † 1		
# participants affected / at risk	**2/132 (1.52%)**	**0/53 (0.00%)**
Haemolytic anaemia † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Hypersplenism † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Leukocytosis † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Lymphadenopathy † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Spleen disorder † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Splenomegaly † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Thrombocytopenia † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**

Cardiac disorders		
Arrhythmia † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Cardiac failure congestive † 1		
# participants affected / at risk	**2/132 (1.52%)**	**0/53 (0.00%)**
Congenital, familial and genetic disorders		
Sickle cell anaemia † 1		
# participants affected / at risk	**0/132 (0.00%)**	**1/53 (1.89%)**
Sickle cell anaemia with crisis † 1		
# participants affected / at risk	**48/132 (36.36%)**	**19/53 (35.85%)**
Ear and labyrinth disorders		
Otorrhoea † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Tinnitus † 1		
# participants affected / at risk	**0/132 (0.00%)**	**1/53 (1.89%)**
Eye disorders		
Vitreous haemorrhage † 1		
# participants affected / at risk	**0/132 (0.00%)**	**1/53 (1.89%)**
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	**14/132 (10.61%)**	**4/53 (7.55%)**
Abdominal pain upper † 1		
# participants affected / at risk	**3/132 (2.27%)**	**1/53 (1.89%)**
Ascites † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**

Constipation † 1		
# participants affected / at risk	**2/132 (1.52%)**	**1/53 (1.89%)**
Dental caries † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Diarrhoea † 1		
# participants affected / at risk	**2/132 (1.52%)**	**1/53 (1.89%)**
Food poisoning † 1		
# participants affected / at risk	**0/132 (0.00%)**	**1/53 (1.89%)**
Gastrointestinal haemorrhage † 1		
# participants affected / at risk	**2/132 (1.52%)**	**0/53 (0.00%)**
Gastrointestinal inflammation † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Nausea † 1		
# participants affected / at risk	**3/132 (2.27%)**	**0/53 (0.00%)**
Pancreatitis † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Pancreatitis acute † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Retroperitoneal haemorrhage † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Tooth disorder † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Varices oesophageal † 1		
# participants affected / at risk	**0/132 (0.00%)**	**1/53 (1.89%)**
Vomiting † 1		

# participants affected / at risk	**7/132 (5.30%)**	**5/53 (9.43%)**
General disorders		
Asthenia † 1		
# participants affected / at risk	**0/132 (0.00%)**	**1/53 (1.89%)**
Catheter related complication † 1		
# participants affected / at risk	**0/132 (0.00%)**	**2/53 (3.77%)**
Catheter site haemorrhage † 1		
# participants affected / at risk	**0/132 (0.00%)**	**1/53 (1.89%)**
Catheter site pain † 1		
# participants affected / at risk	**1/132 (0.76%)**	**1/53 (1.89%)**
Catheter thrombosis † 1		
# participants affected / at risk	**0/132 (0.00%)**	**1/53 (1.89%)**
Chest discomfort † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Chest pain † 1		
# participants affected / at risk	**8/132 (6.06%)**	**4/53 (7.55%)**
Chills † 1		
# participants affected / at risk	**1/132 (0.76%)**	**1/53 (1.89%)**
Facial pain † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Granuloma † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Local swelling † 1		
# participants affected / at risk	**0/132 (0.00%)**	**1/53 (1.89%)**
Necrosis † 1		

# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Non-cardiac chest pain † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Oedema peripheral † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Pain † 1		
# participants affected / at risk	6/132 (4.55%)	1/53 (1.89%)
Pyrexia † 1		
# participants affected / at risk	25/132 (18.94%)	9/53 (16.98%)
Hepatobiliary disorders		
Bile duct stone † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Biliary colic † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Cholecystitis † 1		
# participants affected / at risk	1/132 (0.76%)	1/53 (1.89%)
Cholelithiasis † 1		
# participants affected / at risk	7/132 (5.30%)	2/53 (3.77%)
Hepatic cirrhosis † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Hepatic failure † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Hepatic sequestration † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Hyperbilirubinaemia † 1		

# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Jaundice † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Infections and infestations		
Abscess limb † 1		
# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Adenovirus infection † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Appendicitis † 1		
# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Bacteraemia † 1		
# participants affected / at risk	2/132 (1.52%)	0/53 (0.00%)
Bronchitis † 1		
# participants affected / at risk	3/132 (2.27%)	2/53 (3.77%)
Catheter bacteraemia † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Catheter related infection † 1		
# participants affected / at risk	5/132 (3.79%)	2/53 (3.77%)
Cellulitis † 1		
# participants affected / at risk	3/132 (2.27%)	1/53 (1.89%)
Central line infection † 1		
# participants affected / at risk	1/132 (0.76%)	1/53 (1.89%)
Endocarditis † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Gastroenteritis † 1		

# participants affected / at risk	2/132 (1.52%)	3/53 (5.66%)
Gastroenteritis viral † 1		
# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Herpes zoster † 1		
# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Influenza † 1		
# participants affected / at risk	1/132 (0.76%)	1/53 (1.89%)
Lobar pneumonia † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Lung infection † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Mononucleosis syndrome † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Osteomyelitis † 1		
# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Otitis media † 1		
# participants affected / at risk	1/132 (0.76%)	1/53 (1.89%)
Pharyngitis streptococcal † 1		
# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Pneumonia † 1		
# participants affected / at risk	13/132 (9.85%)	3/53 (5.66%)
Pneumonia bacterial † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Pyelonephritis † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)

Pyelonephritis acute † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Respiratory syncytial virus infection † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Sepsis † 1		
# participants affected / at risk	**3/132 (2.27%)**	**1/53 (1.89%)**
Sinusitis † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Staphylococcal bacteraemia † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Staphylococcal infection † 1		
# participants affected / at risk	**1/132 (0.76%)**	**1/53 (1.89%)**
Staphylococcal sepsis † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Subcutaneous abscess † 1		
# participants affected / at risk	**0/132 (0.00%)**	**1/53 (1.89%)**
Tuberculosis † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Upper respiratory tract infection † 1		
# participants affected / at risk	**3/132 (2.27%)**	**3/53 (5.66%)**
Urinary tract infection † 1		
# participants affected / at risk	**3/132 (2.27%)**	**1/53 (1.89%)**
Viral infection † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Viral upper respiratory tract infection † 1		

# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Injury, poisoning and procedural complications		
Alcohol poisoning † [1]		
# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Arteriovenous fistula thrombosis † [1]		
# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Citrate toxicity † [1]		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Collapse of lung † [1]		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Device failure † [1]		
# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Drug toxicity † [1]		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Excoriation † [1]		
# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Fall † [1]		
# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Haemolytic transfusion reaction † [1]		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Head injury † [1]		
# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Incision site pain † [1]		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Jaw fracture † [1]		

# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Medical device complication † 1		
# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Meniscus lesion † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Overdose † 1		
# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Patella fracture † 1		
# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Transfusion reaction † 1		
# participants affected / at risk	3/132 (2.27%)	0/53 (0.00%)
Vascular graft occlusion † 1		
# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Investigations		
Alanine aminotransferase increased † 1		
# participants affected / at risk	1/132 (0.76%)	1/53 (1.89%)
Aspartate aminotransferase increased † 1		
# participants affected / at risk	1/132 (0.76%)	1/53 (1.89%)
Biopsy liver † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Blood alkaline phosphatase † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Blood amylase increased † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Blood bilirubin increased † 1		

# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Blood iron increased † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Lipase increased † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Oxygen saturation decreased † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Pregnancy test positive † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Total lung capacity decreased † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Transaminases increased † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Metabolism and nutrition disorders		
Decreased appetite † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Dehydration † 1		
# participants affected / at risk	4/132 (3.03%)	1/53 (1.89%)
Hyponatraemia † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Iron overload † 1		
# participants affected / at risk	1/132 (0.76%)	1/53 (1.89%)
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		

# participants affected / at risk	3/132 (2.27%)	2/53 (3.77%)
Back pain † 1		
# participants affected / at risk	6/132 (4.55%)	5/53 (9.43%)
Bone pain † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Bursitis † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Costochondritis † 1		
# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Flank pain † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Muscular weakness † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Musculoskeletal pain † 1		
# participants affected / at risk	3/132 (2.27%)	0/53 (0.00%)
Osteolysis † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Osteonecrosis † 1		
# participants affected / at risk	4/132 (3.03%)	0/53 (0.00%)
Pain in extremity † 1		
# participants affected / at risk	6/132 (4.55%)	3/53 (5.66%)
Rheumatoid arthritis † 1		
# participants affected / at risk	0/132 (0.00%)	1/53 (1.89%)
Rotator cuff syndrome † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)

Synovial cyst † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Chronic myeloid leukaemia † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Lung neoplasm † 1		
# participants affected / at risk	**0/132 (0.00%)**	**1/53 (1.89%)**
Nervous system disorders		
Altered state of consciousness † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Complex partial seizures † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Convulsion † 1		
# participants affected / at risk	**3/132 (2.27%)**	**1/53 (1.89%)**
Dizziness † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Encephalopathy † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Facial palsy † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Haemorrhage intracranial † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Headache † 1		
# participants affected / at risk	**7/132 (5.30%)**	**2/53 (3.77%)**
Hepatic encephalopathy † 1		

# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Hypoaesthesia † 1		
# participants affected / at risk	2/132 (1.52%)	0/53 (0.00%)
Intraventricular haemorrhage † 1		
# participants affected / at risk	1/132 (0.76%)	2/53 (3.77%)
Migraine † 1		
# participants affected / at risk	2/132 (1.52%)	0/53 (0.00%)
Paraesthesia † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Syncope † 1		
# participants affected / at risk	3/132 (2.27%)	0/53 (0.00%)
Transient ischaemic attack † 1		
# participants affected / at risk	3/132 (2.27%)	0/53 (0.00%)
Pregnancy, puerperium and perinatal conditions		
Abortion spontaneous † 1		
# participants affected / at risk	1/132 (0.76%)	1/53 (1.89%)
Pregnancy † 1		
# participants affected / at risk	3/132 (2.27%)	1/53 (1.89%)
Psychiatric disorders		
Abnormal behaviour † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Conversion disorder † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)
Mental status changes † 1		
# participants affected / at risk	1/132 (0.76%)	0/53 (0.00%)

Renal and urinary disorders		
Enuresis † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Haematuria † 1		
# participants affected / at risk	**0/132 (0.00%)**	**1/53 (1.89%)**
Nephropathy toxic † 1		
# participants affected / at risk	**0/132 (0.00%)**	**1/53 (1.89%)**
Oliguria † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Renal failure acute † 1		
# participants affected / at risk	**2/132 (1.52%)**	**0/53 (0.00%)**
Reproductive system and breast disorders		
Breast swelling † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Epididymitis † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Priapism † 1		
# participants affected / at risk	**3/132 (2.27%)**	**1/53 (1.89%)**
Vaginal haemorrhage † 1		
# participants affected / at risk	**0/132 (0.00%)**	**1/53 (1.89%)**
Respiratory, thoracic and mediastinal disorders		
Asthma † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Cough † 1		
# participants affected / at risk	**4/132 (3.03%)**	**0/53 (0.00%)**

Dyspnoea † 1		
# participants affected / at risk	**4/132 (3.03%)**	**1/53 (1.89%)**
Epistaxis † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Lung infiltration † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Oropharyngeal pain † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Pleural effusion † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Pneumonitis † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Productive cough † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Pulmonary hypertension † 1		
# participants affected / at risk	**0/132 (0.00%)**	**2/53 (3.77%)**
Pulmonary thrombosis † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Respiratory failure † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Respiratory tract congestion † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Wheezing † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Skin and subcutaneous tissue disorders		

Skin ulcer † 1		
# participants affected / at risk	**2/132 (1.52%)**	**0/53 (0.00%)**
Swelling face † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Surgical and medical procedures		
Catheter placement † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Catheter removal † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Central venous catheterisation † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Cholecystectomy † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Hip arthroplasty † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Vascular disorders		
Haematoma † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Hypotension † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (0.00%)**
Jugular vein distension † 1		
# participants affected / at risk	**1/132 (0.76%)**	**0/53 (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
ICL670	Participants treated with ICL670 during the Core Study 0109(NCT00067080) and during the extension phase. ICL670 was administered orally once a day based on the participant's body weight.
Crossover	Participants treated with Deferoxamine (DFO) during the Core Study 0109 (NCT00067080) and treated with ICL670 during the extension phase. ICL670 was administered orally once a day based on the participant's body weight.

Other Adverse Events

	ICL670	Crossover
Total, other (not including serious) adverse events		
# participants affected / at risk	**129/132 (97.73%)**	**47/53 (88.68%)**
Blood and lymphatic system disorders		
Leukocytosis † [1]		
# participants affected / at risk	**4/132 (3.03%)**	**3/53 (5.66%)**
Lymphadenopathy † [1]		
# participants affected / at risk	**8/132 (6.06%)**	**2/53 (3.77%)**
Cardiac disorders		

Tachycardia † 1		
# participants affected / at risk	**2/132 (1.52%)**	**3/53 (5.66%)**
Congenital, familial and genetic disorders		
Sickle cell anaemia with crisis † 1		
# participants affected / at risk	**37/132 (28.03%)**	**13/53 (24.53%)**
Ear and labyrinth disorders		
Ear pain † 1		
# participants affected / at risk	**8/132 (6.06%)**	**3/53 (5.66%)**
Eye disorders		
Ocular icterus † 1		
# participants affected / at risk	**11/132 (8.33%)**	**6/53 (11.32%)**
Vision blurred † 1		
# participants affected / at risk	**9/132 (6.82%)**	**5/53 (9.43%)**
Gastrointestinal disorders		
Abdominal discomfort † 1		
# participants affected / at risk	**9/132 (6.82%)**	**2/53 (3.77%)**
Abdominal pain † 1		
# participants affected / at risk	**32/132 (24.24%)**	**13/53 (24.53%)**
Abdominal pain upper † 1		
# participants affected / at risk	**27/132 (20.45%)**	**15/53 (28.30%)**
Constipation † 1		
# participants affected / at risk	**28/132 (21.21%)**	**7/53 (13.21%)**
Diarrhoea † 1		
# participants affected / at risk	**39/132 (29.55%)**	**19/53 (35.85%)**

Dyspepsia † [1]		
# participants affected / at risk	**8/132 (6.06%)**	**3/53 (5.66%)**
Gastrooesophageal reflux disease † [1]		
# participants affected / at risk	**2/132 (1.52%)**	**3/53 (5.66%)**
Nausea † [1]		
# participants affected / at risk	**52/132 (39.39%)**	**19/53 (35.85%)**
Toothache † [1]		
# participants affected / at risk	**9/132 (6.82%)**	**4/53 (7.55%)**
Vomiting † [1]		
# participants affected / at risk	**45/132 (34.09%)**	**17/53 (32.08%)**
General disorders		
Asthenia † [1]		
# participants affected / at risk	**7/132 (5.30%)**	**1/53 (1.89%)**
Chest pain † [1]		
# participants affected / at risk	**24/132 (18.18%)**	**15/53 (28.30%)**
Chills † [1]		
# participants affected / at risk	**9/132 (6.82%)**	**4/53 (7.55%)**
Fatigue † [1]		
# participants affected / at risk	**22/132 (16.67%)**	**7/53 (13.21%)**
Oedema peripheral † [1]		
# participants affected / at risk	**14/132 (10.61%)**	**4/53 (7.55%)**
Pain † [1]		
# participants affected / at risk	**16/132 (12.12%)**	**6/53 (11.32%)**
Pyrexia † [1]		
# participants affected / at risk	**45/132 (34.09%)**	**22/53 (41.51%)**

Hepatobiliary disorders		
Jaundice † [1]		
# participants affected / at risk	**6/132 (4.55%)**	**3/53 (5.66%)**
Infections and infestations		
Bronchitis † [1]		
# participants affected / at risk	**8/132 (6.06%)**	**1/53 (1.89%)**
Cellulitis † [1]		
# participants affected / at risk	**2/132 (1.52%)**	**3/53 (5.66%)**
Ear infection † [1]		
# participants affected / at risk	**9/132 (6.82%)**	**1/53 (1.89%)**
Gastroenteritis † [1]		
# participants affected / at risk	**12/132 (9.09%)**	**3/53 (5.66%)**
Gastroenteritis viral † [1]		
# participants affected / at risk	**8/132 (6.06%)**	**4/53 (7.55%)**
Influenza † [1]		
# participants affected / at risk	**14/132 (10.61%)**	**4/53 (7.55%)**
Nasopharyngitis † [1]		
# participants affected / at risk	**37/132 (28.03%)**	**16/53 (30.19%)**
Oral herpes † [1]		
# participants affected / at risk	**8/132 (6.06%)**	**1/53 (1.89%)**
Pharyngitis † [1]		
# participants affected / at risk	**12/132 (9.09%)**	**4/53 (7.55%)**
Pharyngitis streptococcal † [1]		
# participants affected / at risk	**7/132 (5.30%)**	**4/53 (7.55%)**

Pneumonia † 1		
# participants affected / at risk	**2/132 (1.52%)**	**3/53 (5.66%)**
Rhinitis † 1		
# participants affected / at risk	**9/132 (6.82%)**	**0/53 (0.00%)**
Sinusitis † 1		
# participants affected / at risk	**17/132 (12.88%)**	**5/53 (9.43%)**
Staphylococcal infection † 1		
# participants affected / at risk	**7/132 (5.30%)**	**1/53 (1.89%)**
Tonsillitis † 1		
# participants affected / at risk	**7/132 (5.30%)**	**1/53 (1.89%)**
Upper respiratory tract infection † 1		
# participants affected / at risk	**43/132 (32.58%)**	**19/53 (35.85%)**
Urinary tract infection † 1		
# participants affected / at risk	**20/132 (15.15%)**	**3/53 (5.66%)**
Viral infection † 1		
# participants affected / at risk	**11/132 (8.33%)**	**1/53 (1.89%)**
Injury, poisoning and procedural complications		
Allergic transfusion reaction † 1		
# participants affected / at risk	**1/132 (0.76%)**	**3/53 (5.66%)**
Excoriation † 1		
# participants affected / at risk	**8/132 (6.06%)**	**0/53 (0.00%)**
Skin laceration † 1		
# participants affected / at risk	**4/132 (3.03%)**	**3/53 (5.66%)**
Transfusion reaction † 1		
# participants affected / at risk	**8/132 (6.06%)**	**2/53 (3.77%)**

Investigations		
Alanine aminotransferase increased † 1		
# participants affected / at risk	**6/132 (4.55%)**	**4/53 (7.55%)**
Aspartate aminotransferase increased † 1		
# participants affected / at risk	**8/132 (6.06%)**	**3/53 (5.66%)**
Blood creatinine increased † 1		
# participants affected / at risk	**12/132 (9.09%)**	**4/53 (7.55%)**
Serum ferritin increased † 1		
# participants affected / at risk	**8/132 (6.06%)**	**4/53 (7.55%)**
Transaminases increased † 1		
# participants affected / at risk	**9/132 (6.82%)**	**1/53 (1.89%)**
Metabolism and nutrition disorders		
Decreased appetite † 1		
# participants affected / at risk	**7/132 (5.30%)**	**3/53 (5.66%)**
Dehydration † 1		
# participants affected / at risk	**5/132 (3.79%)**	**4/53 (7.55%)**
Vitamin D deficiency † 1		
# participants affected / at risk	**8/132 (6.06%)**	**5/53 (9.43%)**
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	**36/132 (27.27%)**	**14/53 (26.42%)**
Back pain † 1		
# participants affected / at risk	**48/132 (36.36%)**	**15/53 (28.30%)**
Bone pain † 1		
# participants affected / at risk	**9/132 (6.82%)**	**0/53 (0.00%)**

Muscle spasms † 1		
# participants affected / at risk	**10/132 (7.58%)**	**1/53 (1.89%)**
Muscular weakness † 1		
# participants affected / at risk	**5/132 (3.79%)**	**3/53 (5.66%)**
Musculoskeletal pain † 1		
# participants affected / at risk	**12/132 (9.09%)**	**9/53 (16.98%)**
Myalgia † 1		
# participants affected / at risk	**6/132 (4.55%)**	**4/53 (7.55%)**
Neck pain † 1		
# participants affected / at risk	**3/132 (2.27%)**	**4/53 (7.55%)**
Pain in extremity † 1		
# participants affected / at risk	**41/132 (31.06%)**	**13/53 (24.53%)**
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	**17/132 (12.88%)**	**7/53 (13.21%)**
Headache † 1		
# participants affected / at risk	**61/132 (46.21%)**	**30/53 (56.60%)**
Hypoaesthesia † 1		
# participants affected / at risk	**7/132 (5.30%)**	**1/53 (1.89%)**
Migraine † 1		
# participants affected / at risk	**7/132 (5.30%)**	**4/53 (7.55%)**
Psychiatric disorders		
Anxiety † 1		
# participants affected / at risk	**7/132 (5.30%)**	**3/53 (5.66%)**

Depression † 1		
# participants affected / at risk	**10/132 (7.58%)**	**0/53 (0.00%)**
Insomnia † 1		
# participants affected / at risk	**13/132 (9.85%)**	**2/53 (3.77%)**
Renal and urinary disorders		
Chromaturia † 1		
# participants affected / at risk	**3/132 (2.27%)**	**3/53 (5.66%)**
Proteinuria † 1		
# participants affected / at risk	**7/132 (5.30%)**	**0/53 (0.00%)**
Reproductive system and breast disorders		
Dysmenorrhoea † 1		
# participants affected / at risk	**10/132 (7.58%)**	**4/53 (7.55%)**
Ovarian cyst † 1		
# participants affected / at risk	**1/132 (0.76%)**	**3/53 (5.66%)**
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	**35/132 (26.52%)**	**14/53 (26.42%)**
Dyspnoea † 1		
# participants affected / at risk	**12/132 (9.09%)**	**6/53 (11.32%)**
Epistaxis † 1		
# participants affected / at risk	**8/132 (6.06%)**	**4/53 (7.55%)**
Nasal congestion † 1		
# participants affected / at risk	**22/132 (16.67%)**	**9/53 (16.98%)**
Oropharyngeal pain † 1		
# participants affected / at risk	**40/132 (30.30%)**	**15/53 (28.30%)**

Rhinitis allergic † 1		
# participants affected / at risk	**6/132 (4.55%)**	**3/53 (5.66%)**
Rhinorrhoea † 1		
# participants affected / at risk	**9/132 (6.82%)**	**4/53 (7.55%)**
Skin and subcutaneous tissue disorders		
Acne † 1		
# participants affected / at risk	**5/132 (3.79%)**	**3/53 (5.66%)**
Pruritus † 1		
# participants affected / at risk	**16/132 (12.12%)**	**3/53 (5.66%)**
Rash † 1		
# participants affected / at risk	**21/132 (15.91%)**	**9/53 (16.98%)**
Rash papular † 1		
# participants affected / at risk	**7/132 (5.30%)**	**1/53 (1.89%)**
Urticaria † 1		
# participants affected / at risk	**9/132 (6.82%)**	**4/53 (7.55%)**

† 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
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No publications provided

Responsible Party: External Affairs, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier: NCT01090323 History of Changes

Obsolete Identifiers:	NCT00171197
Other Study ID Numbers:	**CICL670A0109E1**
	EudraCT no. 2004-000597-31 (Registry Identifier: EudraCT)
Study First Received:	March 15, 2010
Results First Received:	December 21, 2010
Last Updated:	May 3, 2011
Health Authority:	United States: Food and Drug Administration
	Italy: Ministry of Health
	Canada: Health Canada
	France: Comité consultatif sur le traitement de l'information en matière de recherche dans le domaine de la santé
	United Kingdom: Medicines and Healthcare Products Regulatory Agency