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Trial record **1 of 1** for: CAMN107X2201

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Efficacy, Safety, Tolerability and Pharmacokinetics (PK) of Nilotinib (AMN107) in Pulmonary Arterial Hypertension (PAH)

This study has been terminated.

(Study was terminated due to serious adverse event (SAE))

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01179737

First received: August 3, 2010
Last updated: April 14, 2014
Last verified: April 2014
History of Changes

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Results First Received: January 14, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Pulmonary Arterial Hypertension
Interventions:	Drug: Nilotinib Drug: Placebo to nilotinib

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
23 participants were enrolled into the study (15 in cohort 1; 8 in cohort 2) 8 participants completed cohort 1 and 6 of these participants moved into cohort 1expansion. Of the 5 participants that completed Cohort 1 expansion; 3 participants went into an Extension. None of the participants completed treatment as trial was terminated

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Participants were randomized 6:1 ratio to nilotinib and placebo

Reporting Groups

	Description
Cohort 1: Nilotinib	Participants were assigned to receive nilotinib 50 mg during 14 days, followed by 150 mg during 14 days, followed by 300 mg during 140 days.
Cohort 1: Placebo	Participants were assigned to receive placebo to nilotinib to match 50 mg and 150 mg capsules during 168 days.
Cohort 2: Nilotinib	Participants were assigned to receive nilotinib 300 mg during 168 days
Cohort 2: Placebo	Participants were assigned to receive placebo to match 50mg and / or 150mg capsules during 168 days

Participant Flow for 3 periods

Period 1: Cohort 1 & Cohort 2

	Cohort 1: Nilotinib	Cohort 1: Placebo	Cohort 2: Nilotinib	Cohort 2: Placebo
STARTED	**12**	**3** [1]	**4**	**4**
COMPLETED	**7**	**1**	**0**	**0**
NOT COMPLETED	**5**	**2**	**4**	**4**
Adverse Event	**3**	**1**	**1**	**0**

Withdrew consent	2	0	0	0
Administrative problems	0	0	2	4
Death	0	0	1	0
Withdrew consent without EOS 1 visit	0	1	0	0

[1] One patient was missing the end of study evaluation

Period 2: Cohort 1 & Cohort 2 Expansion

	Cohort 1: Nilotinib	Cohort 1: Placebo	Cohort 2: Nilotinib	Cohort 2: Placebo
STARTED	5 [1]	1	0	0
COMPLETED	4	1	0	0
NOT COMPLETED	1	0	0	0
Death	1	0	0	0

[1] 2 participants did not enroll in extension

Period 3: Extension

	Cohort 1: Nilotinib	Cohort 1: Placebo	Cohort 2: Nilotinib	Cohort 2: Placebo
STARTED	3 [1]	0 [2]	0	0
COMPLETED	0	0	0	0
NOT COMPLETED	3	0	0	0
The study was terminated	3	0	0	0

[1] Two patients did not enrol in the extension
[2] One patient did not enrol in the extension

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.
an end of study evaluation was only available for 14 of these patients

Reporting Groups

	Description
Cohort 1: Nilotinib	Participants were assigned to receive nilotinib 50 mg during 14 days, followed by 150 mg during 14 days, followed by 300 mg during 140 days.
Cohort 1: Placebo	Participants were assigned to receive placebo to nilotinib to match 50 mg and 150 mg capsules during 168 days.
Cohort 2: Nilotinib	Participants were assigned to receive nilotinib 300 mg during 168 days
Cohort 2: Placebo	Participants were assigned to receive placebo to match 50mg and / or 150mg capsules during 168 days
Total	Total of all reporting groups

Baseline Measures

	Cohort 1: Nilotinib	Cohort 1: Placebo	Cohort 2: Nilotinib	Cohort 2: Placebo	Total
Number of Participants [units: participants]	**12**	**3**	**4**	**4**	**23**
Age [units: Years] Mean (Standard Deviation)	**52 (13.1)**	**60 (6.1)**	**31 (14.6)**	**33 (10.2)**	**32 (11.8)**
Gender [units: Participants]					
Female	**10**	**3**	**4**	**3**	**20**
Male	**2**	**0**	**0**	**1**	**3**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Pulmonary Vascular Resistance (PVR) [Time Frame: 168 days]

Measure Type	Primary
Measure Title	Change in Pulmonary Vascular Resistance (PVR)
Measure Description	Change in pulmonary vascular resistance is measured via right heart catheter assessment according to local hospital procedures. It assesses several prognostic hemodynamic variables in pulmonary hypertension, including Pulmonary Vascular Resistance (PVR). Study was prematurely terminated and not powered for efficacy.
Time Frame	168 days
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
Change in Pulmonary Vascular Resistance (PVR)	Change in pulmonary vascular resistance is measured via right heart catheter assessment according to local hospital procedures. It assesses several prognostic hemodynamic variables in pulmonary hypertension, including Pulmonary Vascular Resistance (PVR). Additional information about the outcome measure, if needed for clarification. Outcome Measures are: Specific key measurement(s) or observation(s) used to measure the effect of experimental variables in a study, or for observational studies, to describe patterns of diseases or traits or associations with exposures, risk factors or treatment. Examples: Title: all cause mortality Time Frame: one year Safety Issue: No Title: Evidence of clinically definite ischemic stroke (focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI Time Frame: within the first 30 days (plus or minus 3 days) after surgery Safety Issue: Yes

Measured Values

	Change in Pulmonary Vascular Resistance (PVR)
Number of Participants Analyzed [units: participants]	**0**
Change in Pulmonary Vascular Resistance (PVR)	

No statistical analysis provided for Change in Pulmonary Vascular Resistance (PVR)

2. Secondary: Change in Six-Minute Walk Distance (6MWD) From Baseline [Time Frame: Baseline, 168 days]

Measure Type	Secondary
Measure Title	Change in Six-Minute Walk Distance (6MWD) From Baseline
Measure Description	During standardized walk course participants are connected to a portable pulse oximeter via a finger probe and instructed to walk at a comfortable speed for as far as they could manage in 6 minutes. Study was prematurely terminated and efficacy data were not analyzed or summarized
Time Frame	Baseline, 168 days
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
Change in Six-Minute Walk Distance (6MWD) From Baseline	During standardized walk course participants are connected to a portable pulse oximeter via a finger probe and instructed to walk at a comfortable speed for as far as they could manage in 6 minu

Measured Values

	Change in Six-Minute Walk Distance (6MWD) From Baseline
Number of Participants Analyzed [units: participants]	**0**
Change in Six-Minute Walk Distance (6MWD) From Baseline	

No statistical analysis provided for Change in Six-Minute Walk Distance (6MWD) From Baseline

3. Secondary: Total Number of Adverse Events and Serious Adverse Events [Time Frame: 168 days]

Measure Type	Secondary
Measure Title	Total Number of Adverse Events and Serious Adverse Events
Measure Description	Adverse events were summarized by the number of patients having any adverse event overall and presented in the safety section. Study was prematurely terminated.
Time Frame	168 days
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
Total Number of Adverse Events and Serious Adverse Events	Adverse events were summarized by the number of patients having any adverse event overall and presented in the safety section.

Measured Values

	Total Number of Adverse Events and Serious Adverse Events
Number of Participants Analyzed [units: participants]	**0**
Total Number of Adverse Events and Serious Adverse Events	

No statistical analysis provided for Total Number of Adverse Events and Serious Adverse Events

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events were collected over the duration of treatment 140 days for cohort 1, 168 days for cohort 2 and up to 1092 days in the extension study
Additional Description	23 participants were enrolled into the study; 8 participants completed cohort 1 and 6 of these participants moved into cohort 1 expansion of which 5 participants completed Cohort 1 expansion. Of the 5 participants, 3 went into an Extension. None of the participants completed treatment as trial was terminated

Reporting Groups

	Description
Cohort 1: Nilotinib	Participants were assigned to receive nilotinib 50 mg during 14 days, followed by 150 mg during 14 days, followed by 300 mg during 140 days.
Cohort 1: Placebo	Participants were assigned to receive placebo to nilotinib to match 50 mg and 150 mg capsules during 168 days.
Cohort 2: Nilotinib	Participants were assigned to receive nilotinib 300 mg during 168 days
Cohort 2: Placebo	Participants were assigned to receive placebo to match 50mg and / or 150mg capsules during 168 days

Serious Adverse Events

	Cohort 1: Nilotinib	Cohort 1: Placebo	Cohort 2: Nilotinib	Cohort 2: Placebo
Total, serious adverse events				

# participants affected / at risk	7/12 (58.33%)	1/3 (33.33%)	2/4 (50.00%)	1/4 (25.00%)
Blood and lymphatic system disorders				
Disseminated intravascular coagulation †1				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
Cardiac disorders				
Cardiogenic shock †1				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
Pulseless electrical activity †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Right ventricular dysfunction †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Torsade de pointes †1				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
Gastrointestinal disorders				
Abdominal pain †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Gastric ulcer haemorrhage †1				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
General disorders				
Chest pain †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Device leakage †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Oedema peripheral †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Hepatobiliary disorders				
Cholecystitis acute †1				

# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Cholecystitis chronic †1				
# participants affected / at risk	3/12 (25.00%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Cholelithiasis †1				
# participants affected / at risk	2/12 (16.67%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Chronic hepatitis †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Infections and infestations				
Bronchitis †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Cellulitis †1				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
Clostridial infection †1				
# participants affected / at risk	0/12 (0.00%)	1/3 (33.33%)	0/4 (0.00%)	0/4 (0.00%)
Infusion site infection †1				
# participants affected / at risk	0/12 (0.00%)	1/3 (33.33%)	0/4 (0.00%)	0/4 (0.00%)
Lobar pneumonia †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Sepsis †1				
# participants affected / at risk	0/12 (0.00%)	1/3 (33.33%)	0/4 (0.00%)	0/4 (0.00%)
Musculoskeletal and connective tissue disorders				
Pathological fracture †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Systemic lupus erythematosus †1				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	0/4 (0.00%)	1/4 (25.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Hepatic neoplasm malignant †1				

# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Metastases to bone †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Renal and urinary disorders				
Renal failure acute †1				
# participants affected / at risk	**0/12 (0.00%)**	**0/3 (0.00%)**	**1/4 (25.00%)**	**0/4 (0.00%)**
Respiratory, thoracic and mediastinal disorders				
Acute respiratory failure †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Dyspnoea †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**1/4 (25.00%)**	**0/4 (0.00%)**
Haemothorax †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Productive cough †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Pulmonary arterial hypertension †1				
# participants affected / at risk	**3/12 (25.00%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Pulmonary oedema †1				
# participants affected / at risk	**0/12 (0.00%)**	**0/3 (0.00%)**	**1/4 (25.00%)**	**0/4 (0.00%)**
Vascular disorders				
Thrombophlebitis superficial †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events were collected over the duration of treatment 140 days for cohort 1, 168 days for cohort 2 and up to 1092 days in the extension study
Additional Description	23 participants were enrolled into the study; 8 participants completed cohort 1 and 6 of these participants moved into cohort 1 expansion of which 5 participants completed Cohort 1 expansion. Of the 5 participants, 3 went into an Extension. None of the participants completed treatment as trial was terminated

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
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Cohort 2: Nilotinib	Participants were assigned to receive nilotinib 300 mg during 168 days
Cohort 2: Placebo	Participants were assigned to receive placebo to match 50mg and / or 150mg capsules during 168 days

Other Adverse Events

	Cohort 1: Nilotinib	**Cohort 1: Placebo**	**Cohort 2: Nilotinib**	**Cohort 2: Placebo**
Total, other (not including serious) adverse events				
# participants affected / at risk	**12/12 (100.00%)**	**1/3 (33.33%)**	**3/4 (75.00%)**	**4/4 (100.00%)**
Blood and lymphatic system disorders				
Anaemia †1				
# participants affected / at risk	**3/12 (25.00%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Bone marrow oedema †1				
# participants affected / at risk	**0/12 (0.00%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**1/4 (25.00%)**
Pancytopenia †1				

# participants affected / at risk	1/12 (8.33%)	1/3 (33.33%)	0/4 (0.00%)	0/4 (0.00%)
Polychromasia [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Red blood cell abnormality [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Cardiac disorders				
Dilatation ventricular [†1]				
# participants affected / at risk	2/12 (16.67%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Left atrial dilatation [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Palpitations [†1]				
# participants affected / at risk	2/12 (16.67%)	0/3 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
Pericardial effusion [†1]				
# participants affected / at risk	2/12 (16.67%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Right ventricular failure [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Right ventricular hypertrophy [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Sinus arrest [†1]				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
Tricuspid valve incompetence [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Ventricular extrasystoles [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	1/4 (25.00%)
Ventricular tachycardia [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Ear and labyrinth disorders				
Tinnitus [†1]				

# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Eye disorders				
Conjunctival hyperaemia †1				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
Eye pain †1				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
Periorbital oedema †1				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
Gastrointestinal disorders				
Abdominal discomfort †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Abdominal distension †1				
# participants affected / at risk	2/12 (16.67%)	0/3 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
Abdominal pain †1				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	0/4 (0.00%)	1/4 (25.00%)
Abdominal pain upper †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
Constipation †1				
# participants affected / at risk	3/12 (25.00%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Diarrhoea †1				
# participants affected / at risk	4/12 (33.33%)	1/3 (33.33%)	1/4 (25.00%)	0/4 (0.00%)
Dry mouth †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Flatulence †1				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	0/4 (0.00%)	1/4 (25.00%)
Gastrooesophageal reflux disease †1				
# participants affected / at risk	2/12 (16.67%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Haemorrhoidal haemorrhage †1				

# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Hypoaesthesia oral [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Mucous stools [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Nausea [†1]				
# participants affected / at risk	3/12 (25.00%)	1/3 (33.33%)	3/4 (75.00%)	1/4 (25.00%)
Vomiting [†1]				
# participants affected / at risk	3/12 (25.00%)	0/3 (0.00%)	3/4 (75.00%)	0/4 (0.00%)
General disorders				
Application site irritation [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Asthenia [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Catheter site inflammation [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Chest discomfort [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Chest pain [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Chills [†1]				
# participants affected / at risk	2/12 (16.67%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Fatigue [†1]				
# participants affected / at risk	6/12 (50.00%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Injection site pain [†1]				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	0/4 (0.00%)	1/4 (25.00%)
Non-cardiac chest pain [†1]				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	0/4 (0.00%)	1/4 (25.00%)

Oedema [†1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Oedema peripheral [†1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/3 (0.00%)**	**1/4 (25.00%)**	**1/4 (25.00%)**
Pain [†1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Pyrexia [†1]				
# participants affected / at risk	**2/12 (16.67%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Infections and infestations				
Candidiasis [†1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Device related infection [†1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Nasopharyngitis [†1]				
# participants affected / at risk	**3/12 (25.00%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**1/4 (25.00%)**
Respiratory tract infection [†1]				
# participants affected / at risk	**0/12 (0.00%)**	**0/3 (0.00%)**	**1/4 (25.00%)**	**0/4 (0.00%)**
Upper respiratory tract infection [†1]				
# participants affected / at risk	**1/12 (8.33%)**	**1/3 (33.33%)**	**0/4 (0.00%)**	**1/4 (25.00%)**
Urinary tract infection [†1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**1/4 (25.00%)**
Urinary tract infection fungal [†1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Viral sinusitis [†1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Viral upper respiratory tract infection [†1]				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Vulvovaginal mycotic infection [†1]				

# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Wound infection staphylococcal †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Injury, poisoning and procedural complications				
Arthropod sting †1				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	0/4 (0.00%)	1/4 (25.00%)
Contusion †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Fall †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Investigations				
Alanine aminotransferase increased †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
Amylase increased †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Aspartate aminotransferase increased †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Biopsy bone †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Blood bilirubin increased †1				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	2/4 (50.00%)	0/4 (0.00%)
Blood calcium decreased †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Blood potassium decreased †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Blood triglycerides increased †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Blood uric acid increased †1				

# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
C-reactive protein increased †1				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	0/4 (0.00%)	1/4 (25.00%)
Electrocardiogram T wave inversion †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Eosinophil count increased †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Haematocrit decreased †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Haemoglobin decreased †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Heart rate increased †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Lipase increased †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	1/4 (25.00%)
Liver function test abnormal †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Lymphocyte count decreased †1				
# participants affected / at risk	1/12 (8.33%)	1/3 (33.33%)	0/4 (0.00%)	0/4 (0.00%)
Neutrophil count decreased †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Platelet count decreased †1				
# participants affected / at risk	1/12 (8.33%)	1/3 (33.33%)	0/4 (0.00%)	0/4 (0.00%)
Platelet count increased †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Red blood cell burr cells present †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Red blood cell count decreased †1				
# participants affected / at risk	2/12 (16.67%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)

Right ventricular systolic pressure increased †1				
# participants affected / at risk	**2/12 (16.67%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Weight decreased †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
White blood cell count decreased †1				
# participants affected / at risk	**1/12 (8.33%)**	**1/3 (33.33%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Metabolism and nutrition disorders				
Decreased appetite †1				
# participants affected / at risk	**3/12 (25.00%)**	**0/3 (0.00%)**	**1/4 (25.00%)**	**0/4 (0.00%)**
Fluid retention †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Hyperglycaemia †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Hypocalcaemia †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Hypoglycaemia †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Hypokalaemia †1				
# participants affected / at risk	**2/12 (16.67%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Musculoskeletal and connective tissue disorders				
Arthralgia †1				
# participants affected / at risk	**0/12 (0.00%)**	**1/3 (33.33%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Back pain †1				
# participants affected / at risk	**2/12 (16.67%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**1/4 (25.00%)**
Muscle spasms †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Musculoskeletal chest pain †1				
# participants affected / at risk	**0/12 (0.00%)**	**1/3 (33.33%)**	**0/4 (0.00%)**	**0/4 (0.00%)**

Musculoskeletal pain †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Musculoskeletal stiffness †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Myalgia †1				
# participants affected / at risk	**0/12 (0.00%)**	**0/3 (0.00%)**	**1/4 (25.00%)**	**0/4 (0.00%)**
Pain in extremity †1				
# participants affected / at risk	**3/12 (25.00%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Lung neoplasm †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Thyroid neoplasm †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Nervous system disorders				
Carpal tunnel syndrome †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Convulsion †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Dizziness †1				
# participants affected / at risk	**0/12 (0.00%)**	**0/3 (0.00%)**	**1/4 (25.00%)**	**0/4 (0.00%)**
Dysgeusia †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Headache †1				
# participants affected / at risk	**6/12 (50.00%)**	**1/3 (33.33%)**	**3/4 (75.00%)**	**1/4 (25.00%)**
Migraine †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Presyncope †1				

# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
Syncope †1				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	0/4 (0.00%)	2/4 (50.00%)
Psychiatric disorders				
Decreased interest †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Depression †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Insomnia †1				
# participants affected / at risk	2/12 (16.67%)	0/3 (0.00%)	0/4 (0.00%)	1/4 (25.00%)
Renal and urinary disorders				
Renal failure acute †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Urinary incontinence †1				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
Reproductive system and breast disorders				
Gynaecomastia †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Pelvic pain †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Vaginal haemorrhage †1				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	0/4 (0.00%)	1/4 (25.00%)
Respiratory, thoracic and mediastinal disorders				
Cough †1				
# participants affected / at risk	4/12 (33.33%)	0/3 (0.00%)	1/4 (25.00%)	1/4 (25.00%)
Diaphragmalgia †1				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Dyspnoea †1				

# participants affected / at risk	2/12 (16.67%)	0/3 (0.00%)	1/4 (25.00%)	1/4 (25.00%)
Epistaxis [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Nasal congestion [†1]				
# participants affected / at risk	3/12 (25.00%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Oropharyngeal pain [†1]				
# participants affected / at risk	2/12 (16.67%)	0/3 (0.00%)	1/4 (25.00%)	0/4 (0.00%)
Productive cough [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Pulmonary arterial hypertension [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Pulmonary oedema [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Rhinorrhoea [†1]				
# participants affected / at risk	2/12 (16.67%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Sinus congestion [†1]				
# participants affected / at risk	0/12 (0.00%)	1/3 (33.33%)	0/4 (0.00%)	0/4 (0.00%)
Skin and subcutaneous tissue disorders				
Alopecia [†1]				
# participants affected / at risk	2/12 (16.67%)	0/3 (0.00%)	0/4 (0.00%)	1/4 (25.00%)
Night sweats [†1]				
# participants affected / at risk	0/12 (0.00%)	0/3 (0.00%)	0/4 (0.00%)	1/4 (25.00%)
Onychalgia [†1]				
# participants affected / at risk	1/12 (8.33%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Pain of skin [†1]				
# participants affected / at risk	3/12 (25.00%)	0/3 (0.00%)	0/4 (0.00%)	0/4 (0.00%)
Pruritus [†1]				
# participants affected / at risk	3/12 (25.00%)	0/3 (0.00%)	1/4 (25.00%)	1/4 (25.00%)

Rash †1				
# participants affected / at risk	**3/12 (25.00%)**	**0/3 (0.00%)**	**2/4 (50.00%)**	**0/4 (0.00%)**
Rash macular †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Skin tightness †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Skin ulcer †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Vascular disorders				
Blood pressure fluctuation †1				
# participants affected / at risk	**0/12 (0.00%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**1/4 (25.00%)**
Flushing †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (0.00%)**
Hypotension †1				
# participants affected / at risk	**1/12 (8.33%)**	**0/3 (0.00%)**	**1/4 (25.00%)**	**0/4 (0.00%)**
Inferior vena cava dilatation †1				
# participants affected / at risk	**2/12 (16.67%)**	**0/3 (0.00%)**	**0/4 (0.00%)**	**0/4 (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 or disclosure of trial results in their entirety

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No publications provided

Responsible Party: Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier: NCT01179737 History of Changes
Obsolete Identifiers: NCT01531270
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