ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 06/11/2012

ClinicalTrials.gov ID: NCT00385203

Study Identification

Unique Protocol ID:	D8480C00046
Brief Title:	The Biological Activity of Cediranib (AZD2171) in Gastro-Intestinal Stromal Tumours(GIST).
Official Title:	An Open-Label, Phase II Study to Evaluate the Biological Activity of Cediranib (AZD2171) as Measured by [F 18] Fluoro 2 Deoxy D Glucose - Positron Emission Tomography (FDG-PET) Response, in Patients With Metastatic Gastro-Intestinal Stromal Tumours (GIST) Resistant or Intolerant to Imatinib Mesylate
Secondary IDs:	

Study Status

Record Verification:	June 2012
Overall Status:	Completed
Study Start:	September 2006
Primary Completion:	June 2008 [Actual]
Study Completion:	December 2009 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes

Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 06/MRE01/50 Board Name: South East Medical Research Ethics Committee Board Affiliation: Central Office for Research Ethics Committees Phone: 0044 (0) 1227 831662 Email: jane-martin@stmrec.fsnet.co.uk
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	United Kingdom: Medicines and Healthcare Products Regulatory Agency

Study Description

Brief Summary:	To determine the anti-tumour activity and biological effects of cediranib (AZD2171) at a dose of 45mg, primarily in Gastrointestinal Stromal Tumour (GIST) patients who are resistant to imatinib mesylate (current standard therapy) and also in patients with metastatic Soft Tissue Sarcoma (STS) resistant to standard therapy.
Detailed Description:	

Conditions

Conditions:	Gastrointestinal Stromal Tumors Soft Tissue Sarcomas
Keywords:	cancer tumour advanced cancer Metastatic Gastro-Intestinal Stromal Tumours gastro-intestinal cancer RECENTIN

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2

Intervention Model:	Single Group Assignment
Number of Arms:	1
Masking:	Open Label
Allocation:	Non-Randomized
Endpoint Classification:	Efficacy Study
Enrollment:	35 [Actual]

Arms and Interventions

Intervention Details:

Drug: AZD2171

45 mg oral tablet once daily dose

Other Names:

- cediranib
- RECENTIN™

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

- Histological or cytological confirmation of GIST which is resistant or intolerant to imatinib mesylate, or metastatic STS, which is refractory to standard therapies or for which no standard therapy exists

Exclusion Criteria:

- Patients with type I insulin-dependent diabetes or poorly-controlled type II insulin-independent diabetes.
- Patients with a history of poorly controlled high blood pressure

Contacts/Locations

Study Officials: Jane Robertson, MD
Study Director
AstraZeneca

Locations: United Kingdom
Research Site
Sutton, United Kingdom

Research Site
Manchester, United Kingdom

References

Citations:

Links: URL: http://www.astrazeneca.com/node/emailtriage.aspx
Description Astrazeneca Information - outside of the US

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	Enrolled: 45mg GIST=26, 45mg STS=10; Full analysis set: 45mg GIST=25, 45mg STS=10; Safety set: 45mg GIST=24, 45mg STS=10. 36 patients were enrolled and 35 patients were randomized. One GIST patient consented but had an adverse event and was withdrawn from the study before they were randomised.

Reporting Groups

	Description
Cediranib 45 mg/Day GIST	26 Gastrointestinal Stromal tumour patients (GIST) were enrolled (informed consent received), one patient was enrolled but had an AE prior to randomisation so were withdrawn from the study. No demographic data were obtained for this patient.
Cediranib 45 mg/Day STS	10 Soft Tissue Sarcomas (STS) patients were randomised.

Overall Study

	Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day STS
Started	26	10
Completed	0	3
Not Completed	26	7
Adverse Event	5	4
Death	1	0
Condition under investigation worsened	18	3
Incorrect enrollment	2	0

Baseline Characteristics

Reporting Groups

	Description
Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day: 25 patients with Gastrointestinal Stromal Tumour (GIST) randomised
Cediranib 45 mg/Day STS	Cediranib 45 mg/Day: 10 patients with Soft Tissue Sarcomas (STS) randomised

Baseline Measures

	Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day STS	Total
Number of Participants	25	10	35
Age, Continuous [1] [units: years] Mean (Standard Deviation)	56.1 (9.8)	44.6 (9.4)	52.8 (10.9)
Gender, Male/Female [2] [units: participants]			
Female	8	6	14
Male	17	4	21

[1] Age at informed consent

[2] Gender at informed consent

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change in Standardised Uptake Value (SUV)Max at Day 8, Central Review, (GIST) Gastrointestinal Stromal Tumours Patients.
Measure Description	[F 18] Fluoro 2 Deoxy D Glucose - Positron Emission Tomography (FDG-PET). Tumour metabolic activity as assessed by Change in Standardised Uptake Value (SUVMax) at Day 8 (measured by central review), in Patients with GIST tumours. SUVmax at Day 8 minus SUVmax at Baseline.
Time Frame	Baseline and 8 days after dosing.
Safety Issue?	No

Analysis Population Description

As per the protocol the analysis was for GIST patients only (not STS patients). For patients to be included in the analysis they had to have scans with readable results at both timepoints (baseline and Day 8).

Reporting Groups

	Description
Cediranib 45 mg/Day GIST	26 Gastrointestinal Stromal tumour patients (GIST) were enrolled (informed consent received), one patient was enrolled but had an AE prior to randomisation so were withdrawn from the study. No demographic data were obtained for this patient.
Cediranib 45 mg/Day STS	Cediranib 45 mg/Day patients with Soft Tissue Sarcomas (STS): 10 patients randomised and received at least one dose of treatment

Measured Values

	Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day STS
Number of Participants Analyzed	22	0
Change in Standardised Uptake Value (SUV)Max at Day 8, Central Review, (GIST) Gastrointestinal Stromal Tumours Patients. [units: g/mL] Mean (95% Confidence Interval)	-0.515 (-1.480 to 0.450)	

2. Primary Outcome Measure:

Measure Title	Tumour Metabolic Activity as Assessed by Change in Central Review of Standardised Uptake Value (SUVMax) at Day 29, in Patients With GIST Tumours. SUVmax at Day 29 Minus SUVmax at Baseline.

Measure Description	SUVmax at Day 29 minus SUVmax at baseline, based on central review, GIST patients
Time Frame	FDG-PET assessment at Baseline and 29 days after dosing.
Safety Issue?	No

Analysis Population Description

As per the protocol the analysis was for GIST patients only (not STS patients). For patients to be included in the analysis they had to have scans with readable results at both timepoints (baseline and Day 29).

Reporting Groups

	Description
Cediranib 45 mg/Day GIST	26 Gastrointestinal Stromal tumour patients (GIST) were enrolled (informed consent received), one patient was enrolled but had an AE prior to randomisation so were withdrawn from the study. No demographic data were obtained for this patient.
Cediranib 45 mg/Day STS	10 Soft Tissue Sarcomas (STS) patients were randomised.

Measured Values

	Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day STS
Number of Participants Analyzed	20	0
Tumour Metabolic Activity as Assessed by Change in Central Review of Standardised Uptake Value (SUVMax) at Day 29, in Patients With GIST Tumours. SUVmax at Day 29 Minus SUVmax at Baseline. [units: g/mL] Mean (95% Confidence Interval)	-0.172 (-1.380 to 1.040)	

3. Secondary Outcome Measure:

Measure Title	Objective Tumour Response, Investigator Review
Measure Description	Number of patients with complete (CR) /partial response (PR) (based on RECIST) as assessed by the Investigator. CR is defined as Disappearance of all target lesions. PR is defined as at least a 30% decrease in the sum of Longest Diameter (LD) of target lesions taking as reference the baseline sum LD.
Time Frame	RECIST at Baseline, Weeks 8, 16 and every 12 weeks thereafter until progression.
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Cediranib 45 mg/Day GIST	26 Gastrointestinal Stromal tumour patients (GIST) were enrolled (informed consent received), one patient was enrolled but had an AE prior to randomisation so were withdrawn from the study. No demographic data were obtained for this patient.
Cediranib 45 mg/Day STS	10 Soft Tissue Sarcomas (STS) patients were randomised.

Measured Values

	Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day STS
Number of Participants Analyzed	24	10
Objective Tumour Response, Investigator Review [units: Participants]	0	4

4. Secondary Outcome Measure:

Measure Title	-Tumour Activity as Measured by Major Axis (Axial Plane) at Week 8 in GIST/STS Patients by Central Review of CT Images.
Measure Description	Central review of CT images taking the longest diameter measured in millimetres at week 8 [major axis (axial plane)] minus the longest diameter measured in millimetres at baseline.
Time Frame	CT assessments at Baseline and Week 8
Safety Issue?	No

Analysis Population Description

As per the protocol the formal statistical analysis was performed for the GIST grouppatients only, STS patients were summarised (not STS patients). For patients to be included in the analysis they had to have CT scans at both timepoints (baseline and week 8).

Reporting Groups

	Description
Cediranib 45 mg/Day GIST	26 Gastrointestinal Stromal tumour patients (GIST) were enrolled (informed consent received), one patient was enrolled but had an AE prior to randomisation so were withdrawn from the study. No demographic data were obtained for this patient.
Cediranib 45 mg/Day STS	10 Soft Tissue Sarcomas (STS) patients were randomised.

Measured Values

	Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day STS
Number of Participants Analyzed	18	8
-Tumour Activity as Measured by Major Axis (Axial Plane) at Week 8 in GIST/STS Patients by Central Review of CT Images. [units: mm] Mean (95% Confidence Interval)	2.734 (-1.76 to 7.230)	-1.015 (-7.22 to 5.19)

5. Secondary Outcome Measure:

Measure Title	Anti-tumour Activity as Measured by Major Axis (Axial Plane) at Week 16 in GIST/STS Patients by Central Review of CT Images.
Measure Description	Central review of CT images taking the longest diameter measured in millimetres at week 16 [major axis (axial plane)] minus the longest diameter measured in millimetres at baseline.
Time Frame	CT assessments at Baseline and Week 16.
Safety Issue?	No

Analysis Population Description

As per the protocol formal statistical analysis was performed for the GIST group only, STS patients were summarised. For patients to be included in the analysis they had to have CT scans at both timepoints (baseline and week 8).

Reporting Groups

	Description
Cediranib 45 mg/Day GIST	26 Gastrointestinal Stromal tumour patients (GIST) were enrolled (informed consent received), one patient was enrolled but had an AE prior to randomisation so were withdrawn from the study. No demographic data were obtained for this patient.
Cediranib 45 mg/Day STS	10 Soft Tissue Sarcomas (STS) patients were randomised.

Measured Values

	Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day STS
Number of Participants Analyzed	13	5
Anti-tumour Activity as Measured by Major Axis (Axial Plane) at Week 16 in GIST/STS Patients by Central Review of CT Images. [units: mm] Mean (95% Confidence Interval)	5.028 (-1.120 to 11.180)	-8.114 (-15.74 to -0.49)

6. Secondary Outcome Measure:

Measure Title	Tumour Activity as Measured by Total Lesion Volume at Week 8 in GIST Patients by Central Review of CT Images.
Measure Description	Central review of CT images taking the total lesion volume at week 8 minus the total lesion volume at baseline.
Time Frame	CT assessments at Baseline and Week 8
Safety Issue?	No

Analysis Population Description

As per the protocol formal statistical analysis was performed for the GIST group only, STS patients were summarised. For patients to be included in the analysis they had to have CT scans at both timepoints (baseline and week 8).

Reporting Groups

	Description
Cediranib 45 mg/Day GIST	26 Gastrointestinal Stromal tumour patients (GIST) were enrolled (informed consent received), one patient was enrolled but had an AE prior to randomisation so were withdrawn from the study. No demographic data were obtained for this patient.
Cediranib 45 mg/Day STS	10 Soft Tissue Sarcomas (STS) patients were randomised.

Measured Values

	Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day STS
Number of Participants Analyzed	18	8
Tumour Activity as Measured by Total Lesion Volume at Week 8 in GIST Patients by Central Review of CT Images. [units: cm3] Mean (95% Confidence Interval)	19889.31 (-7054.96 to 46833.58)	5106.30 (-21840.10 to 32052.70)

7. Secondary Outcome Measure:

Measure Title	Anti-tumour Activity as Measured by Total Lesion Volume at Week 16 in GIST Patients by Central Review of CT Images.
Measure Description	Central review of CT images taking the total lesion volume at week 16 minus the total lesion volume at baseline.
Time Frame	CT assessments at Baseline and Week 16

Safety Issue?	No

Analysis Population Description

As per the protocol formal statistical analysis was performed for the GIST group only, STS patients were summarised. For patients to be included in the analysis they had to have CT scans at both timepoints (baseline and week 8).

Reporting Groups

	Description
Cediranib 45 mg/Day GIST	26 Gastrointestinal Stromal tumour patients (GIST) were enrolled (informed consent received), one patient was enrolled but had an AE prior to randomisation so were withdrawn from the study. No demographic data were obtained for this patient.
Cediranib 45 mg/Day STS	10 Soft Tissue Sarcomas (STS) patients were randomised.

Measured Values

	Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day STS
Number of Participants Analyzed	13	5
Anti-tumour Activity as Measured by Total Lesion Volume at Week 16 in GIST Patients by Central Review of CT Images. [units: cm3] Mean (95% Confidence Interval)	43202.54 (-4505.18 to 90910.27)	-6479.65 (-15411.92 to 2452.63)

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	Adverse events are reported for randomised patients who received at least one dose of treatment.

Reporting Groups

	Description
Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day patients with Gastrointestinal Stromal Tumour (GIST): 24 patients randomised and received at least one dose of treatment (1 patient was not randomised or dosed and a further 1 patient was randomised but not dosed due to Incorrect enrolmentCediranib)
Cediranib 45 mg/Day STS	Cediranib 45 mg/Day patients with Soft Tissue Sarcomas (STS): 10 patients randomised and received at least one dose of treatment.

Serious Adverse Events

	Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day STS
	Affected/At Risk (%)	Affected/At Risk (%)
Total	10/24 (41.67%)	3/10 (30%)
Gastrointestinal disorders		
Abdominal Discomfort [A] †	1/24 (4.17%)	0/10 (0%)
Abdominal Pain [A] †	1/24 (4.17%)	1/10 (10%)
Constipation [A] †	1/24 (4.17%)	0/10 (0%)
Diarrhoea [A] †	1/24 (4.17%)	0/10 (0%)
Intestinal Obstruction [A] †	1/24 (4.17%)	0/10 (0%)
Vomiting [A] †	1/24 (4.17%)	0/10 (0%)
General disorders		
Fatigue [A] †	1/24 (4.17%)	0/10 (0%)
Non-Cardiac Chest Pain [A] †	1/24 (4.17%)	0/10 (0%)
Hepatobiliary disorders		
Hepatic Haemorrhage [A] †	1/24 (4.17%)	0/10 (0%)
Jaundice [A] †	1/24 (4.17%)	0/10 (0%)
Metabolism and nutrition disorders		
Dehydration [A] †	1/24 (4.17%)	0/10 (0%)
Nervous system disorders		
Cerebrovascular Accident [A] †	1/24 (4.17%)	0/10 (0%)
Convulsion [A] †	0/24 (0%)	1/10 (10%)
Psychiatric disorders		
Psychotic Disorder [A] †	1/24 (4.17%)	0/10 (0%)
Renal and urinary disorders		

	Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day STS
	Affected/At Risk (%)	Affected/At Risk (%)
Renal Impairment [A] †	1/24 (4.17%)	0/10 (0%)
Respiratory, thoracic and mediastinal disorders		
Pulmonary Embolism [A] †	1/24 (4.17%)	0/10 (0%)
Vascular disorders		
Anaemia [A] †	1/24 (4.17%)	0/10 (0%)
Hypertension [A] †	0/24 (0%)	1/10 (10%)
Hypertensive Crisis [A] †	1/24 (4.17%)	0/10 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 12.1

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day STS
	Affected/At Risk (%)	Affected/At Risk (%)
Total	24/24 (100%)	10/10 (100%)
Blood and lymphatic system disorders		
Anaemia [A] †	2/24 (8.33%)	0/10 (0%)
Thrombocytopenia [A] †	0/24 (0%)	1/10 (10%)
Cardiac disorders		
Palpitations [A] †	0/24 (0%)	3/10 (30%)
Splinter Haemorrhages [A] †	0/24 (0%)	1/10 (10%)
Tachycardia [A] †	1/24 (4.17%)	2/10 (20%)
Endocrine disorders		
Hypothyroidism [A] †	5/24 (20.83%)	2/10 (20%)
Gastrointestinal disorders		

	Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day STS
	Affected/At Risk (%)	Affected/At Risk (%)
Abdominal Discomfort [A] †	4/24 (16.67%)	1/10 (10%)
Abdominal Distension [A] †	4/24 (16.67%)	0/10 (0%)
Abdominal Pain [A] †	5/24 (20.83%)	3/10 (30%)
Abdominal Pain Upper [A] †	4/24 (16.67%)	1/10 (10%)
Constipation [A] †	9/24 (37.5%)	2/10 (20%)
Diarrhoea [A] †	20/24 (83.33%)	8/10 (80%)
Dry Mouth [A] †	2/24 (8.33%)	2/10 (20%)
Dyspepsia [A] †	0/24 (0%)	1/10 (10%)
Glossodynia [A] †	1/24 (4.17%)	2/10 (20%)
Mouth Haemorrhage [A] †	0/24 (0%)	1/10 (10%)
Mouth Ulceration [A] †	3/24 (12.5%)	2/10 (20%)
Nausea [A] †	7/24 (29.17%)	2/10 (20%)
Oral Pain [A] †	5/24 (20.83%)	2/10 (20%)
Stomatitis [A] †	6/24 (25%)	4/10 (40%)
Toothache [A] †	1/24 (4.17%)	1/10 (10%)
Vomiting [A] †	3/24 (12.5%)	0/10 (0%)
General disorders		
Fatigue [A] †	17/24 (70.83%)	7/10 (70%)
Mucosal Inflammation [A] †	0/24 (0%)	1/10 (10%)
Oedema Peripheral [A] †	4/24 (16.67%)	1/10 (10%)
Pyrexia [A] †	1/24 (4.17%)	4/10 (40%)
Hepatobiliary disorders		

	Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day STS
	Affected/At Risk (%)	Affected/At Risk (%)
Hyperbilirubinaemia [A] †	0/24 (0%)	1/10 (10%)
Infections and infestations		
Furuncle [A] †	2/24 (8.33%)	0/10 (0%)
Gastric Infection [A] †	0/24 (0%)	1/10 (10%)
Lower Respiratory Tract Infection [A] †	0/24 (0%)	1/10 (10%)
Oral Herpes [A] †	0/24 (0%)	1/10 (10%)
Pneumonia [A] †	1/24 (4.17%)	1/10 (10%)
Tooth Infection [A] †	1/24 (4.17%)	1/10 (10%)
Upper Respiratory Tract Infection [A] †	1/24 (4.17%)	2/10 (20%)
Urinary Tract Infection [A] †	4/24 (16.67%)	0/10 (0%)
Viral Infection [A] †	0/24 (0%)	2/10 (20%)
Injury, poisoning and procedural complications		
Contusion [A] †	0/24 (0%)	1/10 (10%)
Muscle Strain [A] †	2/24 (8.33%)	0/10 (0%)
Investigations		
Transaminases Increased [A] †	0/24 (0%)	1/10 (10%)
Weight Decreased [A] †	6/24 (25%)	2/10 (20%)
Weight Increased [A] †	0/24 (0%)	1/10 (10%)
Metabolism and nutrition disorders		
Decreased Appetite [A] †	13/24 (54.17%)	4/10 (40%)
Musculoskeletal and connective tissue disorders		
Arthralgia [A] †	4/24 (16.67%)	4/10 (40%)
Back Pain [A] †	4/24 (16.67%)	1/10 (10%)

	Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day STS
	Affected/At Risk (%)	Affected/At Risk (%)
Joint Swelling [A] †	0/24 (0%)	2/10 (20%)
Muscle Spasms [A] †	1/24 (4.17%)	1/10 (10%)
Musculoskeletal Pain [A] †	0/24 (0%)	2/10 (20%)
Myalgia [A] †	2/24 (8.33%)	0/10 (0%)
Neck Pain [A] †	2/24 (8.33%)	0/10 (0%)
Pain In Extremity [A] †	5/24 (20.83%)	1/10 (10%)
Nervous system disorders		
Ageusia [A] †	0/24 (0%)	1/10 (10%)
Dizziness [A] †	2/24 (8.33%)	0/10 (0%)
Dysgeusia [A] †	1/24 (4.17%)	2/10 (20%)
Headache [A] †	8/24 (33.33%)	3/10 (30%)
Hyperaesthesia [A] †	0/24 (0%)	1/10 (10%)
Sciatica [A] †	1/24 (4.17%)	1/10 (10%)
Somnolence [A] †	0/24 (0%)	1/10 (10%)
Psychiatric disorders		
Anxiety [A] †	2/24 (8.33%)	0/10 (0%)
Depressed Mood [A] †	0/24 (0%)	1/10 (10%)
Hallucination [A] †	2/24 (8.33%)	0/10 (0%)
Insomnia [A] †	3/24 (12.5%)	0/10 (0%)
Renal and urinary disorders		
Proteinuria [A] †	0/24 (0%)	1/10 (10%)
Reproductive system and breast disorders		
Amenorrhoea [A] †	0/24 (0%)	1/10 (10%)

	Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day STS
	Affected/At Risk (%)	Affected/At Risk (%)
Dysmenorrhoea [A] †	0/24 (0%)	1/10 (10%)
Respiratory, thoracic and mediastinal disorders		
Asthma [A] †	0/24 (0%)	1/10 (10%)
Cough [A] †	2/24 (8.33%)	1/10 (10%)
Dysphonia [A] †	12/24 (50%)	4/10 (40%)
Dyspnoea [A] †	3/24 (12.5%)	0/10 (0%)
Epistaxis [A] †	4/24 (16.67%)	2/10 (20%)
Haemoptysis [A] †	0/24 (0%)	1/10 (10%)
Oropharyngeal Pain [A] †	2/24 (8.33%)	2/10 (20%)
Pharyngeal Erythema [A] †	1/24 (4.17%)	1/10 (10%)
Pleuritic Pain [A] †	0/24 (0%)	1/10 (10%)
Skin and subcutaneous tissue disorders		
Blister [A] †	0/24 (0%)	1/10 (10%)
Dermatitis [A] †	0/24 (0%)	1/10 (10%)
Dermatitis Acneiform [A] †	0/24 (0%)	1/10 (10%)
Dry Skin [A] †	3/24 (12.5%)	1/10 (10%)
Palmar-Plantar Erythrodysaesthesia Syndrome [A] †	3/24 (12.5%)	2/10 (20%)
Pruritus [A] †	2/24 (8.33%)	0/10 (0%)
Skin Disorder [A] †	1/24 (4.17%)	1/10 (10%)
Skin Haemorrhage [A] †	1/24 (4.17%)	1/10 (10%)
Subcutaneous Nodule [A] †	0/24 (0%)	1/10 (10%)
Vascular disorders		

	Cediranib 45 mg/Day GIST	Cediranib 45 mg/Day STS
	Affected/At Risk (%)	Affected/At Risk (%)
Hypertension [A] †	19/24 (79.17%)	4/10 (40%)
Hypotension [A] †	0/24 (0%)	1/10 (10%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 12.1

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

If a Study Site, or an investigator, requests permission to publish data from this study, any such publication (including oral presentations) is to be agreed with AstraZeneca prior to publication.

Results Point of Contact:

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