Clevidipine in the Treatment of Patients With Acute Hypertension and Intracerebral Hemorrhage (ACCELERATE) (ACCELERATE)

ClinicalTrials.gov Identifier: NCT00666328

Recruitment Status : Completed
First Posted : April 24, 2008
Results First Posted : April 8, 2013
Last Update Posted : August 29, 2014

Sponsor:

The Medicines Company

Information provided by (Responsible Party):

The Medicines Company

Study Type	Interventional
Study Design	Allocation: N/A; Intervention Model: Single Group Assignment; Masking: None (Open Label); Primary Purpose: Treatment
Conditions	Hypertension Hemorrhage
Intervention	Drug: clevidipine
Enrollment	37

Participant Flow

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Recruitment Details	Patients considered for inclusion in this study were recruited from June 2008 through April 2010 primarily from hospital emergency departments and Neurology Intensive Care Units, having presented with acute hypertension and intracerebral hemorrhage (ICH). Enrollment targeted a subset of ~10 patients requiring intracranial pressure (ICP) monitoring.
Pre-assignment Details	Participants were required to have a systolic blood pressure (SBP) greater than 160 mm Hg both prior to enrollment and immediately prior to study drug initiation. Participants with SBP </=160 mm Hg immediately prior to study drug did not receive clevidipine and were treated per standard of care.

Arm/Group Title	Clevidipine

▼ Arm/Group Description	Clevidipine was administered to eligible participants via intravenous infusion at a starting dose of 2.0 mg/h for 1.5 minutes. Clevidipine was titrated to effect thereafter by doubling the dose every 1.5 minutes, as tolerated by the patient, up to a maximum dose of 32 mg/h, to lower blood pressure within the protocol specific target range (SBP ≤160 mmHg to ≥140 mmHg) for a minimum of 30 minutes and up to 96 hours.

Period Title: **Overall Study**

Started	35 [1]
Modified Intent To Treat (mITT)	33 [2]
Completed	30 [3]
Not Completed	5
Reason Not Completed	
Death	2
Lost to Follow-up	2
No longer met eligibility criteria	1

[1] Safety population: participants dosed with study drug (primary population for Safety analyses)

[2] mITT population: participants dosed and in whom all inclusion and no exclusion criteria were met

[3] 30/35 completed the study within the Safety population; 28/33 completed within the mITT population.

Baseline Characteristics

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Arm/Group Title	Clevidipine
▼ Arm/Group Description	mITT (Modified Intent To Treat) Population (n=33): This population is the primary population for the efficacy analyses.

		Clevidipine was administered to eligible participants via intravenous infusion at a starting dose of 2.0 mg/h for 1.5 minutes. Clevidipine was titrated to effect thereafter by doubling the dose every 1.5 minutes, as tolerated by the patient, up to a maximum dose of 32 mg/h, to lower blood pressure within the protocol specific target range (SBP ≤160 mmHg to ≥140 mmHg) for a minimum of 30 minutes and up to 96 hours. Clevidipine was titrated up or down as necessary to maintain blood pressure within the target range.	
Overall Number of Baseline Participants		33	
▼ Baseline Analysis Population Description		[Not Specified]	
Age, Continuous Mean (Standard Deviation) Unit of measure: Participants			
	Number Analyzed	33 participants	
		63.9 (12.14)	
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants			
	Number Analyzed	33 participants	
	Female	7	21.2%
	Male	26	78.8%
Ethnicity (NIH/OMB) Measure Type: Count of Participants Unit of measure: Participants			
	Number Analyzed	33 participants	
	Hispanic or Latino	4	12.1%
	Not Hispanic or Latino	29	87.9%

	Unknown or Not Reported	0	0.0%
Race/Ethnicity, Customized Measure Type: Number Unit of measure: Participants	Number Analyzed	33 participants	
American Indian or Alaskan Native		0	
Asian		3	
Black or African American		9	
Native Hawaiian or Pacific Islander		0	
White		21	
Baseline Systolic Blood Pressure (SBP) Mean (Standard Deviation) Unit of measure: Mm Hg			
	Number Analyzed	33 participants	
		186.5 (20.39)	
Baseline Diastolic Blood Pressure (DBP) Mean (Standard Deviation) Unit of measure: Mm Hg			
	Number Analyzed	33 participants	
		85.7 (12.89)	

Outcome Measures

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1. Primary Outcome

Title	Median Time to Achieve Target SBP Range (≤160 mmHg to ≥140 mmHg) Within 30 Minutes of Initiation of

	Clevidipine

▼ Description	The median time, in minutes, was estimated with its two-tailed 95% confidence interval from the time of the initiation of clevidipine infusion until the first observed SBP was achieved in the target range of ≤160 mmHg to ≥140 mmHg within the first 30 minutes of clevidipine treatment. If patients did not reach the blood pressure target range within the first 30 minutes, their data was considered censored at 30 minutes. If another IV and/or oral antihypertensive agent indicated for hypertension was administered less than 30 minutes prior to achieving the endpoint, the data was considered censored at the time when the additional or alternative antihypertensive agent was given.
Time Frame	Within 30 minutes of study drug initiation

▼ Outcome Measure Data

▼ Analysis Population Description
Modified Intent To Treat (mITT) population: all participants dosed with clevidipine and in whom all inclusion criteria and none of the exclusion criteria were met.

Arm/Group Title	Clevidipine
▼ Arm/Group Description:	Clevidipine was administered via intravenous infusion at a starting dose of 2.0 mg/h for 1.5 minutes and titrated to effect thereafter by doubling the dose every 1.5 minutes, as tolerated by the patient, up to a maximum dose of 32 mg/h, to lower blood pressure within the protocol specific target range (SBP ≤160 mmHg to ≥140 mmHg). Clevidipine was titrated up or down, as necessary, to maintain blood pressure within the target range for a minimum of 30 minutes to a maximum of 96 hours.
Overall Number of Participants Analyzed	33
Median (95% Confidence Interval) Unit of Measure:	

minutes	

	5.5 (3 to 10)

2. Secondary Outcome

Title	Percentage of Participants Achieving a SBP of ≤160 mmHg Within 30 Minutes of Initiation of Clevidipine
▼ Description	The percentage of patients who reached SBP of ≤160 mmHg within the first 30 minutes of initiation of clevidipine infusion was summarized. If an additional or alternative IV antihypertensive agent and/or oral antihypertensive agent was administered for hypertension prior to a patient achieving SBP≤160 mmHg during the initial 30-minute treatment period, then the patient was considered to have failed to reach this efficacy endpoint.
Time Frame	Within 30 minutes of study drug initiation

▼ Outcome Measure Data

▼ Analysis Population Description
Modified Intent To Treat (mITT) population: all participants dosed with clevidipine and in whom all inclusion criteria and none of the exclusion criteria were met.

Arm/Group Title	Clevidipine
▼ Arm/Group Description:	Clevidipine was administered via intravenous infusion at a starting dose of 2.0 mg/h for 1.5 minutes and titrated to effect thereafter by doubling the dose every 1.5 minutes, as tolerated by the patient, up to a maximum dose of 32 mg/h, to lower blood pressure within the protocol specific target range (SBP ≤160 mmHg to ≥140 mmHg). Clevidipine was titrated up or down, as necessary, to maintain blood pressure within the target range for a minimum of 30 minutes to a maximum of 96 hours.
Overall Number of Participants Analyzed	33

Measure Type: Number Number (95% Confidence Interval) Unit of Measure: percent participants	
	97 (84.2 to 99.9)

3. Secondary Outcome

Title	Percent Change From Baseline in Systolic Blood Pressure During the Initial 30 Minutes of Clevidipine Infusion
▼ Description	Over the initial 30 minutes of the treatment period, the percent change from baseline (defined as immediately prior to study drug initiation) was summarized descriptively at 1, 2, 3, 4, 5, 6, 7, 10, 15, 20, 25, and 30 minutes after clevidipine initiation. Decreases in SBP from baseline were observed over the course of this time period.
Time Frame	Baseline through 30 minutes post initiation of clevidipine infusion

▼ Outcome Measure Data

▼ Analysis Population Description
[Not Specified]

Arm/Group Title	Clevidipine
▼ Arm/Group Description:	Clevidipine was administered via intravenous infusion at a starting dose of 2.0 mg/h for 1.5 minutes and titrated to effect thereafter by doubling the dose every 1.5 minutes, as tolerated by the patient, up to a maximum dose of 32 mg/h, to lower blood pressure within the protocol specific target range (SBP ≤160 mmHg to ≥140 mmHg). Clevidipine was titrated up or down, as necessary, to maintain blood pressure within the target range for a minimum of 30 minutes to a maximum of 96 hours.

Overall Number of Participants Analyzed	33
Mean (Standard Deviation) Unit of Measure: percent change in SBP	
Baseline Through Initial 1 Min.	-2.2 (5.76)
Baseline Through Initial 2 Min.	-4.7 (9.43)
Baseline Through Initial 3 Min.	-5.9 (8.95)
Baseline Through Initial 4 Min.	-8.5 (8.54)
Baseline Through Initial 5 Min.	-9.8 (9.15)
Baseline Through Initial 6 Min.	-11.3 (10.54)
Baseline Through Initial 7 Min.	-13.9 (9.92)
Baseline Through Initial 10 Min.	-14.0 (11.52)
Baseline Through Initial 15 Min.	-17.4 (12.20)
Baseline Through	-17.4 (11.75)

Baseline Through Initial 20 Min.	-17.4 (11.75)

Baseline Through Initial 25 Min.	-18.9 (10.68)
Baseline Through Initial 30 Min.	-20.0 (8.16)

4. Secondary Outcome

Title	Magnitude, Frequency and Duration of Systolic Blood Pressure Excursions (Calculated as Area Under the Curve [AUC]) Outside the Target Range Normalized Per Hour for the Duration of the Clevidipine Monotherapy Infusion
▼ Description	Total AUC-SBP captures the magnitude and duration of SBP either above the upper limit of the target SBP range at 160 mm Hg or below the lower limit of 140 mm Hg and normalized per hour for the duration of clevidipine infusion. A larger value for AUC-SBP indicates greater SBP variability outside the target range.
Time Frame	Duration of the study drug infusion (up to 96 hours)

▼ Outcome Measure Data

▼ Analysis Population Description
[Not Specified]

Arm/Group Title	Clevidipine
▼ Arm/Group Description:	Clevidipine was administered via intravenous infusion at a starting dose of 2.0 mg/h for 1.5 minutes and titrated to effect thereafter by doubling the dose every 1.5 minutes, as tolerated by the patient, up to a maximum dose of 32 mg/h to lower blood pressure within the protocol specific target range (SBP ≤160 mmHg to ≥140 mmHg) for 30 minutes to 96 hours. Clevidipine was titrated up or down as necessary to maintain blood pressure within the target range.
Overall Number of Participants	33

Participants Analyzed	

Mean (Standard Deviation) Unit of Measure: mm Hg × min/hr	
	347.7 (323.06)

5. Secondary Outcome

Title	Percent Time Blood Pressures Were Maintained Within the Target Range (Systolic Blood Pressure ≤160 mmHg to ≥140 mmHg) Over Each 24 Hour Period During Monotherapy Infusion of Clevidipine
▼ Description	The percent time that SBP was maintained within the SBP target range (≤160 mmHg to ≥140 mmHg) was summarized for each 24-hour period of monotherapy of clevidipine infusion through 96 hours (0 -≤24 h, 24-≤48 h, 48-≤72 h, 72-≤96 h). For purposes of this analysis, SBP data were available from all mITT patients for the overall infusion period and from 0 to ≤24 hours of infusion; however, data was only available for 8 patients from 24 to ≤48 hours, 4 patients from 48 to ≤72 hours and 1 patient from 72 to ≤96 hours due to the variability in infusion durations >24 hours across patients.
Time Frame	From study drug initiation through termination (up to 96 h)

▼ Outcome Measure Data

▼ Analysis Population Description
The Modified Intent-to-Treat (mITT) population, defined as all enrolled patients who are eligible for the study (i.e., meet all the inclusion criteria and do not meet any of the exclusion criteria) and treated with clevidipine infusion, population will be the primary population for the efficacy analyses.

Arm/Group Title	Clevidipine

▼ Arm/Group Description:	Clevidipine was administered via intravenous infusion at a starting dose of 2.0 mg/h for 1.5 minutes and titrated to effect thereafter by doubling the dose every 1.5 minutes, as tolerated by the patient, up to a maximum dose of 32 mg/h, to lower blood pressure within the protocol specific target range (SBP ≤160 mmHg to ≥140 mmHg). Clevidipine was titrated up or down, as necessary, to maintain blood pressure within the target range for a minimum of 30 minutes to a maximum of 96 hours.
Overall Number of Participants Analyzed	33
Mean (Standard Deviation) Unit of Measure: percent time	
0 -≤24 h of clevidipine infusion; n=33	51.91 (25.46)
24-≤48 h of clevidipine infusion; n=8	61.12 (21.14)
48-≤72 h of clevidipine infusion; n=4	46.94 (33.25)
72-≤96 h of clevidipine infusion; n=1	65.91 (0.00)

6. Secondary Outcome

Title	Mean Dose of Clevidipine During the Treatment Period

Title	Mean Dose of Clevidipine During the Treatment Period
▼ Description	Mean total dose of clevidipine from study drug initiation to the end of clevidipine treatment

Time Frame	Up to 96 hours

▼ Outcome Measure Data

▼ Analysis Population Description
The Safety population is defined as all enrolled patients who are dosed with clevidipine. This population serves as the primary population for the safety analyses.

Arm/Group Title	Clevidipine
▼ Arm/Group Description:	Clevidipine was administered via intravenous infusion at a starting dose of 2.0 mg/h for 1.5 minutes and titrated to effect thereafter by doubling the dose every 1.5 minutes, as tolerated by the patient, up to a maximum dose of 32 mg/h, to lower blood pressure within the protocol specific target range (SBP ≤160 mmHg to ≥140 mmHg). Clevidipine was titrated up or down, as necessary, to maintain blood pressure within the target range for a minimum of 30 minutes to a maximum of 96 hours.
Overall Number of Participants Analyzed	35
Mean (Standard Deviation) Unit of Measure: milligrams (mg)	
	260.28 (321.68)

7. Secondary Outcome

Title	Median Dose of Clevidipine During the Treatment Period
▼ Description	Mean total dose of clevidipine from study drug initiation to the end of clevidipine treatment
Time Frame	Up to 96 hours

Time Frame	Up to 96 hours

▼ Outcome Measure Data

▼ Analysis Population Description
[Not Specified]

Arm/Group Title	Clevidipine
▼ Arm/Group Description:	Clevidipine was administered via intravenous infusion at a starting dose of 2.0 mg/h for 1.5 minutes and titrated to effect thereafter by doubling the dose every 1.5 minutes, as tolerated by the patient, up to a maximum dose of 32 mg/h, to lower blood pressure within the protocol specific target range (SBP ≤160 mmHg to ≥140 mmHg). Clevidipine was titrated up or down, as necessary, to maintain blood pressure within the target range for a minimum of 30 minutes to a maximum of 96 hours
Overall Number of Participants Analyzed	35
Median (Inter-Quartile Range) Unit of Measure: milligrams (mg)	
	116.32 (0.7 to 1213.8)

8. Secondary Outcome

Title	Proportion of Patients Requiring an Additional or Alternative Antihypertensive Agent(s) With or Without Clevidipine
▼ Description	Additional or alternative antihypertensive agent(s) comprise the use of other antihypertensive agent(s) either with clevidipine (additional) or in place of clevidipine (alternative) for the indication of hypertension from the time of clevidipine initiation to clevidipine termination. For purposes of this analysis, additional or alternative antihypertensive agents did not include oral antihypertensives that were administered in order to transition IV

	clevidipine-treated patients to oral therapy during the transition period of the study.
Time Frame	Up to 96 hours

▼ Outcome Measure Data

▼ Analysis Population Description

The Modified Intent-to-Treat (mITT) population, defined as all enrolled patients who are eligible for the study (i.e., meet all the inclusion criteria and do not meet any of the exclusion criteria) and treated with clevidipine infusion, population will be the primary population for the efficacy analyses.

Arm/Group Title	Clevidipine
▼ Arm/Group Description:	Clevidipine was administered via intravenous infusion at a starting dose of 2.0 mg/h for 1.5 minutes and titrated to effect thereafter by doubling the dose every 1.5 minutes, as tolerated by the patient, up to a maximum dose of 32 mg/h, to lower blood pressure within the protocol specific target range (SBP ≤160 mmHg to ≥140 mmHg). Clevidipine was titrated up or down, as necessary, to maintain blood pressure within the target range for a minimum of 30 minutes to a maximum of 96 hours.
Overall Number of Participants Analyzed	33
Measure Type: Number Unit of Measure: participants	
	18

9. Secondary Outcome

Title	Percent Change in Heart Rate During 30 of Initiation of Clevidipine
▼ Description	Multiple timepoints were assessed (minutes 1, 2, 3, 4, 5, 10, 15, 20, 30) for analysis of percent change in heart rate during the initial 30 minutes.
Time Frame	From study drug initiation through each specified timepoint

Time Frame	From study drug initiation through each specified timepoint

▼ Outcome Measure Data

▼ Analysis Population Description

The Safety population is defined as all enrolled patients who are dosed with clevidipine. This population serves as the primary population for the safety analyses. Data for 33 of the 35 patients in the Safety population had data for the 30 minute time point used for this analysis.

Arm/Group Title	Clevidipine
▼ Arm/Group Description:	Clevidipine was administered via intravenous infusion at a starting dose of 2.0 mg/h for 1.5 minutes and titrated to effect thereafter by doubling the dose every 1.5 minutes, as tolerated by the patient, up to a maximum dose of 32 mg/h, to lower blood pressure within the protocol specific target range (SBP ≤160 mmHg to ≥140 mmHg). Clevidipine was titrated up or down, as necessary, to maintain blood pressure within the target range for a minimum of 30 minutes to a maximum of 96 hours.
Overall Number of Participants Analyzed	35
Mean (Standard Deviation) Unit of Measure: percent change	
Study Drug Initiation Through Initial 1 Min; n=35	-0.4 (5.02)
Study Drug Initiation Through Initial 2 Min; n=32	-0.7 (5.30)
Study Drug Initiation Through Initial 3 Min; n=35	-0.3 (6.41)

Study Drug Initiation Through Initial 4 Min; n=34	0.2 (8.22)
Study Drug Initiation Through Initial 5 Min; n=34	2.1 (8.25)
Study Drug Initiation Through Initial 6 Min; n=34	2.6 (7.73)
Study Drug Initiation Through Initial 7 Min; n=34	2.5 (9.30)
Study Drug Initiation Through Initial 10 Min; n=34	5.6 (13.67)
Study Drug Initiation Through Initial 15 Min; n=35	5.5 (15.65)
Study Drug Initiation Through Initial 20 Min, n=35	6.2 (15.44)
Study Drug Initiation Through Initial 25 Min; n=35	5.4 (14.50)
Baseline Through Initial 30 Mins; n=33	4.9 (14.41)

10. Secondary Outcome

Title	The Percentage of Patients Whose Systolic Blood Pressure is <90 mmHg Within 30 Minutes of the Initiation of Clevidipine Infusion
▼ Description	[Not Specified]
Time Frame	Within 30 minutes of the initiation of study drug infusion

▼ Outcome Measure Data

▼ Analysis Population Description
The Safety population is defined as all enrolled patients who are dosed with clevidipine. This population serves as the primary population for the safety analyses.

Arm/Group Title	Clevidipine
▼ Arm/Group Description:	Clevidipine was administered via intravenous infusion at a starting dose of 2.0 mg/h for 1.5 minutes and titrated to effect thereafter by doubling the dose every 1.5 minutes, as tolerated by the patient, up to a maximum dose of 32 mg/h, to lower blood pressure within the protocol specific target range (SBP ≤160 mmHg to ≥140 mmHg). Clevidipine was titrated up or down, as necessary, to maintain blood pressure within the target range for a minimum of 30 minutes to a maximum of 96 hours.
Overall Number of Participants Analyzed	35
Measure Type: Number Unit of Measure: percent participants	
	0

Adverse Events

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Time Frame	AEs occurring from initiation of clevidipine infusion until up to 6 hours after cessation of clevidipine and SAEs that occurred from initiation of clevidipine infusion until up to 7 days after cessation of clevidipine infusion were assessed.
Adverse Event Reporting Description	[Not Specified]

Arm/Group Title	Clevidipine
▼ Arm/Group Description	Safety Population (n=35): This population is the primary population for the safety analyses. Clevidipine was administered to eligible participants via intravenous infusion at a starting dose of 2.0 mg/h for 1.5 minutes. Clevidipine was titrated to effect thereafter by doubling the dose every 1.5 minutes, as tolerated by the patient, up to a maximum dose of 32 mg/h, to lower blood pressure within the protocol specific target range (SBP ≤160 mmHg to ≥140 mmHg) for a minimum of 30 minutes and up to 96 hours. Clevidipine was titrated up or down as necessary to maintain blood pressure within the target range.

All-Cause Mortality

	Clevidipine
	Affected / at Risk (%)
Total	--/--

▼ Serious Adverse Events

	Clevidipine

	Affected / at Risk (%)
Total	9/35 (25.71%)
Cardiac disorders	
Cardio-respiratory arrest † 1 [1]	1/35 (2.86%)
Supraventricular tachycardia † 1 [1]	1/35 (2.86%)
Nervous system disorders	
Brain oedema † 1 [2]	2/35 (5.71%)
Cerebral haematoma † 1 [1]	1/35 (2.86%)
Convulsion † 1 [2]	1/35 (2.86%)
Haemorrhage intracranial † 1 [2]	1/35 (2.86%)
Intraventricular haemorrhage † 1 [1]	1/35 (2.86%)
Respiratory, thoracic and mediastinal disorders	
Pneumonia aspiration † 1 [1]	1/35 (2.86%)
Respiratory failure † 1	1/35 (2.86%)

† Indicates events were collected by systematic assessment
1 Term from vocabulary, MedDRA 11.0
[1] unrelated
[2] unlikely related

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%
	Clevidipine
	Affected / at Risk (%)
Total	27/35 (77.14%)
Blood and lymphatic system disorders	
Leukocytosis † 1	2/35 (5.71%)
Gastrointestinal disorders	
N… † 1	2/35 (5.71%)

Nausea † 1	3/35 (8.57%)
Vomitting † 1	2/35 (5.71%)
General disorders	
Pyrexia † 1	7/35 (20.00%)
Investigations	
Blood creatinine increased † 1	2/35 (5.71%)
Prothrombin time prolonged † 1	2/35 (5.71%)
White blood cell count increased † 1	2/35 (5.71%)
Metabolism and nutrition disorders	
Hyperglycaemia † 1	2/35 (5.71%)
Hypertriglyceridaemia † 1	3/35 (8.57%)
Hypokalaemia † 1	3/35 (8.57%)
Hypomagnesaemia † 1	2/35 (5.71%)
Hyposphataemia † 1	4/35 (11.43%)
Nervous system disorders	
Headache † 1	5/35 (14.29%)
Psychiatric disorders	
Agitation † 1	4/35 (11.43%)
Renal and urinary disorders	
Urinary retention † 1	2/35 (5.71%)
Respiratory, thoracic and mediastinal disorders	
Rhonchi † 1	2/35 (5.71%)
Vascular disorders	
Hypotension † 1 [1]	3/35 (8.57%)

† Indicates events were collected by systematic assessment

1 Term from vocabulary, MedDRA 11.0

[1]

1 patient (2.86%) discontinued study drug due to a TEAE of hypotension(baseline SBP 82/47 mm Hg). This was a non-serious AE moderate in severity and related to study treatment. The AE lasted 51 min and resolved 29 minutes after study drug withdrawal.

Limitations and Caveats

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[Not Specified]

More Information

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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 site agrees that it will not publish until the earlier of presentation and publication of results or until 12 months after study conclusion. The sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period of 90 days from the time submitted to the sponsor for review in order to allow sponsor time to file any patent applications. The sponsor cannot require changes to the communication and cannot extend the embargo.

Results Point of Contact

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Responsible Party:	The Medicines Company
ClinicalTrials.gov Identifier:	NCT00666328 History of Changes
Other Study ID Numbers:	TMC-CLV-07-02
First Submitted:	April 22, 2008
First Posted:	April 24, 2008
Results First Submitted:	July 25, 2012

Results First Posted:	April 8, 2013
Last Update Posted:	August 29, 2014