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Intravenous Ganaxolone as Adjunctive Therapy to Treat Subjects With Status Epilepticus

ClinicalTrials.gov ID ⓘ **NCT03350035**

Sponsor ⓘ Marinus Pharmaceuticals

Information provided by ⓘ Marinus Pharmaceuticals (Responsible Party)

Last Update Posted ⓘ 2023-03-09



Feedback

Study Details

Researcher View

Results Posted

Record History

Study Record Versions

- This table shows all the versions of this study record arranged in order by submitted date.
 - To view one version of the study record, click the submitted date.
 - To compare two versions, select them using the check boxes and click "Compare" at the bottom of the list.

	Version	Date submitted (YYYY-MM-DD)	Changes
☐	1	2017-11-17	None (earliest version on record)
☐	2	2018-09-27	- Recruitment Status - Study Status - Contacts/Locations - Study Description - Arms and Interventions - Eligibility
☐	3	2019-05-30	- Study Status - Contacts/Locations
☐	4	2019-09-23	- Study Status - Outcome Measures
☐	5	2019-12-23	- Recruitment Status - Study Status - Study Design
☐	6	2020-09-25	Study Status
☐	7	2020-10-16	- Study Status - Arms and Interventions
☐	8	2022-09-28	- Study Status - Outcome Measures - Baseline Characteristics

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			- Adverse Events - Participant Flow - More Information - Document Section	Feedback
			Quality Control Review Has Not Concluded Returned: 2022-10-24	
☐	9	2022-11-18	- Study Status - Outcome Measures - Baseline Characteristics - Adverse Events	Feedback
☐	10	2023-03-08	- Study Status - Document Section	Feedback

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Study Record Versions

Study Details

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Contacts/Locations

IPDSharing

References

Document Section

Version 1: 2017-11-17

Study Details

Study Identification

Unique Protocol ID	1042-SE-2001
Brief Title	Intravenous Ganaxolone as Adjunctive Therapy to Treat Subjects With Status Epilepticus
Official Title	A Double-Blind Randomized, Placebo Controlled Study to Evaluate the Safety, Tolerability, Efficacy, and Pharmacokinetics of Intravenous Ganaxolone as Adjunctive Therapy to Treat Subjects With Status Epilepticus
Secondary IDs	

Feedback

Study Status

Record Verification	2017-11
Overall Status	Not yet recruiting
Study Start	2017-11 [Estimated]
Primary Completion	2019-12 [Estimated]
Study Completion	2019-12 [Estimated]
First Submitted	2017-11-17
First Submitted that Met QC Criteria	2017-11-17
First Posted	2017-11-22
Last Update Submitted that Met QC Criteria	2017-11-17
Last Update Posted	2017-11-22 [Actual]

Feedback

Sponsor/Collaborators

Sponsor	Marinus Pharmaceuticals
Responsible Party	Sponsor
Collaborators	

Feedback

Oversight

U.S. FDA-regulated Drug	Yes
U.S. FDA-regulated Device	No
Data Monitoring	Yes



Study Description

Brief Summary	This study will evaluate the effectiveness and safety of an investigational drug, IV ganaxolone, as adjunctive therapy to standard of care to treat subjects with status epilepticus.
Detailed Description	This is a double-blind, randomized, placebo-controlled study to evaluate the safety, tolerability, and efficacy of adjunctive IV ganaxolone in subjects with SE. Study drug will be added to standard of care before IV anesthetic during the treatment of SE. Subjects will be screened for inclusion/exclusion criteria prior to receiving study drug as adjunctive therapy by continuous IV. Subject's will be followed up for 3 weeks post-treatment.



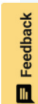
Conditions

Condition	Status Epilepticus Convulsive Status EPILEPTICUS Non Convulsive Status Epilepticus Epilepsy
Keywords	



Study Design

Study Type	Interventional
Primary Purpose	Treatment
Study Phase	Phase 2
Interventional Study Model	Parallel Assignment
Interventional Model Description	Double-blind study that will randomize subjects to ganaxolone or placebo in a 1:1 ratio as adjunctive therapy to their standard of care.
Number of Arms	2
Masking	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Masking Description	
Allocation	Randomized
Enrollment	250 [Estimated]



Arms and Interventions

Arms	Assigned Interventions
Experimental: IV Ganaxolone active	Drug: Ganaxolone
Ganaxolone IV loading dose with continuous infusion (maintenance dose) for 2-4 days followed by a 24-hour taper.	IV

Placebo Comparator: IV Placebo, non-active

Drug: Placebo

Placebo IV loading dose with continuous infusion (maintenance dose) for 2-4 days followed by a 24-hour taper.

- IV



Outcome Measures

Primary Outcome Measures

1. SE Cessation
Control of Status Epilepticus
[Time Frame: 24 hours post study drug initiation]



Eligibility

Minimum Age	12 Years
Maximum Age	
Sex	All
Gender-based Eligibility	
Gender Eligibility Description	
Accepts Healthy Volunteers	No
Criteria	Inclusion Criteria: • Subjects 12 years of age and older • Clinical and/or electrographic seizures Exclusion Criteria: • Life expectancy of less than 24 hours • Anoxic brain injury as primary cause of SE • Administered anesthesia for the treatment of SE • Subjects who are intubated for the administration of IV anesthetics to treat SE. Subjects who are intubated for airway protection are not excluded • Use of pressors except as maintenance therapy for anesthetic use associated with hypotension



Contacts/Locations

Central Contact Person	• Name	Heather Van Heusen, M.Ed.
	Telephone	484-801-4682
	Email	hvanheusen@marinuspharma.com
	• Name	Julia Tsai, PhD
	Telephone	203-215-5820
	Email	jtsai@marinuspharma.com
Study Officials	• Name	Lorianne Masuoka, MD
	Role	Study Director
	Affiliation	Marinus Pharmaceuticals
Location		



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