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Xenon for Neuroprotection During Post-Cardiac Arrest Syndrome in Comatose Survivors of an Out of Hospital Cardiac Arrest (XePOHCAS)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03176186

Recruitment Status ❓ : Recruiting
First Posted ❓ : June 5, 2017
Last Update Posted ❓ : March 8, 2019

See Contacts and Locations

Sponsor:
NeuroproteXeon, Inc.

Information provided by (Responsible Party):
NeuroproteXeon, Inc.

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

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Brief Summary:
XePOHCAS: Prospective, randomized, multicenter interventional trial in adult subjects with out-of-hospital cardiac arrest comparing treatment with standard-of-care post-cardiac arrest intensive care (which is targeted temperature management (TTM) to xenon by inhalation plus standard-of-care post-cardiac arrest intensive care (including TTM).

Condition or disease ❓	Intervention/treatment ❓	Phase ❓
Post-Cardiac Arrest Syndrome	Combination Product: Xenon	Phase 3

Detailed Description:
XePOHCAS:
Primary Objective:
To evaluate whether there is a difference in functional outcome with xenon 50% and oxygen during targeted temperature management (TTM) compared with similar oxygen content in air during TTM in comatose subjects with sustained restoration of spontaneous circulation (ROSC) within 30 minutes after out-of-hospital cardiac arrest (OHCA).
Secondary Objective:
To evaluate whether there is a difference in survival with xenon 50% and oxygen during targeted temperature management (TTM) compared with similar oxygen content in air during TTM in comatose subjects with sustained restoration of spontaneous circulation (ROSC) within 30 minutes after out-of-hospital cardiac arrest (OHCA).

Study Design

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Study Type ❓ :	Interventional (Clinical Trial)
Estimated Enrollment ❓ :	1436 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Single (Outcomes Assessor)
Primary Purpose:	Treatment
Official Title:	XePOHCAS - Xenon by Inhalation for Post Out of Hospital Cardiac Arrest Syndrome
Actual Study Start Date ❓ :	December 20, 2018
Estimated Primary Completion Date ❓ :	October 15, 2020
Estimated Study Completion Date ❓ :	December 15, 2020

Resource links provided by the National Library of Medicine NIH NLM

MedlinePlus related topics: Cardiac Arrest Health Facilities

Drug Information available for: Xenon

U.S. FDA Resources

Arms and Interventions

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Arm ❓	Intervention/treatment ❓
No Intervention: TH/TTM Protocol-directed standard of care (including TH/TTM) dictated by the 2015 guidelines for Post-Cardiac Arrest Care from the American Heart Association and the European Resuscitation Council. Mechanical Ventilation delivered by individual site-sanctioned ventilator.	
Active Comparator: TH/TTM plus Xenon 50% xenon gas in addition to standard of care, including therapeutic hypothermia/targeted temperature management (TH/TTM).	Combination Product: Xenon 50% xenon by inhalation, delivered by customized xenon delivery system, that includes a ventilator, for the 24h period of TH/TTM. The inhalation therapy is provided in combination with protocol-directed Post-Cardiac Arrest Care dictated by the 2015 guidelines from the American Heart Association and the European Resuscitation Council. Other Name: XENEX

Outcome Measures

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Primary Outcome Measures ❓ :
1. functional outcome: degree of functional independence measured using a modified Rankin Scale (mRS) [Time Frame: 30 days after the cardiac arrest]
   The degree of functional independence will be measured using a modified Rankin Scale (mRS)

Secondary Outcome Measures ❓ :
1. survival: number of survivors [Time Frame: 30 days after the cardiac arrest]
   The number of survivors will be measured

Eligibility Criteria

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Information from the National Library of Medicine NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years to 80 Years (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:
1. Age at least 18 years but less than or equal to 80 years
2. Presumed cardiac cause of arrest
3. Sustained (>20 minutes) spontaneous circulation upon arrival in the emergency department
4. No response to verbal commands on arrival to emergency department and prior to randomization (Glasgow Coma Scale score of <8)
5. Attending decision that patient is eligible for TTM

Exclusion Criteria:
1. Written do not attempt resuscitation reported to providers before randomization
2. Traumatic etiology of arrest, defined as concomitant blunt, penetrating, or burn-related injury, or uncontrolled bleeding or exsanguination
3. Suspected or known stroke or intracranial hemorrhage
4. Unwitnessed cardiac arrest
5. No-flow (cardiac arrest to initiation of cardiopulmonary resuscitation/defibrillation) time of >10 minutes
6. Sustained restoration of spontaneous circulation (ROSC) greater than 30- minutes post-arrest
7. Interval from arrival at the emergency department to randomization for intervention of >4 hours.
8. Hypothermia (<30°C core temperature)
9. Bed-bound prior to cardiac arrest
10. Unconsciousness before cardiac arrest (cerebral trauma, spontaneous cerebral hemorrhage, intoxication etc.)
11. Coagulopathy
12. Systolic arterial pressure <80 mmHg or mean arterial pressure <60 mmHg lasting more than 30 minutes after ROSC
13. Known pregnancy
14. Have received an investigational drug, device, or biologic product within 30-days
15. Known terminal phase of chronic illness
16. Hypoxemia (SaO2 <85%) for >15 minutes after ROSC
17. Inability to maintain SaO2 >90% on an FiO2 of 50%
18. Having any other clinically significant laboratory abnormality, medical condition (such as intrinsic liver disease or severe chronic obstructive pulmonary disease), or social circumstance that, in the investigator's opinion, makes it inappropriate for the patient to participate in this clinical trial
19. Logistically impossible to provide intervention
20. Have any condition that would impact the evaluation of modified Rankin Scale (mRS)

Contacts and Locations

Go to

Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

*Please refer to this study by its ClinicalTrials.gov identifier (NCT number): **NCT03176186***

Contacts

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Sponsors and Collaborators
NeuroproteXeon, Inc.

Investigators
Study Director: Myron B Peterson, M.D cro
Study Director: David Franklin, M.B., B.Ch., cro

More Information

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Additional Information:
Phase 2 RCT that forms the basis for this clinical trial

Publications:
Laitio R, Hynninen M, Arola O, Virtanen S, Parkkola R, Saunavaara J, Roine RO, Grönlund J, Yliokoski E, Wennervirta J, Bäcklund M, Silvasti P, Nukarinen E, Tainen M, Saraste A, Pietilä M, Airakisnen J, Valanne L, Martola J, Silvennoinen H, Scheinin H, Harjola VP, Niiranen J, Korpi K, Varpula M, Inkinen O, Olkkola KT, Maze M, Vahlberg T, Laitio T. Effect of Inhaled Xenon on Cerebral White Matter Damage in Comatose Survivors of Out-of-Hospital Cardiac Arrest: A Randomized Clinical Trial. JAMA. 2016 Mar 15;315(11):1120-8. doi: 10.1001/jama.2016.1933.

Responsible Party:	NeuroproteXeon, Inc.
ClinicalTrials.gov Identifier:	NCT03176186 History of Changes
Other Study ID Numbers:	XePOHCAS Ph III
First Posted:	June 5, 2017 Key Record Dates
Last Update Posted:	March 8, 2019
Last Verified:	March 2019

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	Yes
Plan Description:	Authorized representatives of the SITE OF STUDY CONDUCT or other associated health care providers as authorized.

Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	Yes
Device Product Not Approved or Cleared by U.S. FDA:	Yes

Keywords provided by NeuroproteXeon, Inc.:
ischemic-reperfusion injury
out of hospital cardiac arrest

Additional relevant MeSH terms:

Heart Arrest	Xenon
Out-of-Hospital Cardiac Arrest	Anesthetics, Inhalation
Syndrome	Anesthetics, General
Disease	Anesthetics
Pathologic Processes	Central Nervous System Depressants
Heart Diseases	Physiological Effects of Drugs
Cardiovascular Diseases	

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