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Trial record **2 of 75** for: Epilepsy | Wisconsin, United States

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Cerebral Oxygen Saturation and Cytochrome Oxidase REDOX State in Children With Epilepsy: A Pilot Study



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. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT03054961

[Recruitment Status](#) ⓘ : Suspended (Protocol Amendment in process, pending reengineering of instruments)

[First Posted](#) ⓘ : February 16, 2017

[Last Update Posted](#) ⓘ : July 2, 2021

Sponsor:

Medical College of Wisconsin

Collaborator:

Marquette University

Information provided by (Responsible Party):

Harry T Whelan, MD, Medical College of Wisconsin


[Study Details](#)[Tabular View](#)[No Results Posted](#)[Disclaimer](#)[How to Read a Study Record](#)**Study Description**[Go to](#) **Brief Summary:**

The purpose of this pilot study is to describe the relationship of regional cerebral oximetry and cytochrome c oxidase (CCO) redox state and blood oxygen saturation, measured using near-infrared spectroscopy, with seizure activity in the periictal period in children with epilepsy.

<u>Condition or disease</u> ⓘ	<u>Intervention/treatment</u> ⓘ
Epilepsies, Partial	Device: Near-infrared spectroscopy

Detailed Description:

Pediatric subjects with partial (focal) epilepsy seizure disorders who are being admitted to the epilepsy monitoring unit will be studied using near-infrared spectroscopy for cytochrome c oxidase (CCO) redox state and blood oxygen saturation. Along with routine EEG monitoring, a set of light sensors, called optodes, attached to a net that goes over the head will be put on. These optodes will send out very weak red light signals, which will pass through the scalp and bounce back to detectors on the netting. The changes in the light signals will be used to calculate the changes in the various forms of the enzyme CCO, as well as the amount of oxygen in the blood. We hope to use these measurements to study changes in blood flow and cellular energy usage in the brain during seizures, which might help us to understand epilepsy better in the future and design better treatments.

Study Design[Go to](#) **Study Type ⓘ :**

Observational

Estimated Enrollment ⓘ :

40 participants

Observational Model:

Cohort

Time Perspective:

Prospective

Official Title:

Cerebral Oxygen Saturation and Cytochrome Oxidase REDOX State in Children With **Epilepsy**: A Pilot Study - Multichannel Near-infrared Spectroscopy (NIRS) for **Epilepsy** Seizure Detection

Actual Study Start Date ⓘ :

February 10, 2017

Estimated Primary Completion Date ⓘ :

February 9, 2022

Estimated Study Completion Date ⓘ :

February 9, 2024

Resource links provided by the National Library of Medicine

MedlinePlus Genetics related topics: [Pyridoxal 5'-phosphate-dependent epilepsy](#)
[Autosomal dominant partial epilepsy with auditory features](#)

MedlinePlus related topics: [Epilepsy](#) [Oxygen Therapy](#) [Seizures](#)

U.S. FDA Resources

Groups and Cohorts

Go to

<u>Group/Cohort ⓘ</u>	<u>Intervention/treatment ⓘ</u>
Epilepsy patients Near-infrared spectroscopy for subjects with partial (focal) epilepsy seizures being studied in the EMU.	Device: Near-infrared spectroscopy Measurement of CCO redox state and cerebral oxygenation during epileptic seizures.

Outcome Measures

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Primary Outcome Measures ⓘ :

1. Change in CCO redox state and oxygen saturation [Time Frame: 1 week]

Regional cerebral saturation of oxygen and/or cytochrome oxidase redox state will change prior, during, and after onset of seizure activity when compared to non-seizure side of brain.

Information from the National Library of Medicine

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:

up to 18 Years (Child, Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Sampling Method:

Non-Probability Sample

Study Population

Study subjects will include pediatric patients from birth to 18 years of age with a known seizure disorder who are being admitted to the epilepsy monitoring unit (EMU) or the ICU for further workup or medication management of their epilepsy.

Criteria**Inclusion Criteria:**

Study subjects will include pediatric patients from birth to 18 years of age with a known seizure disorder who are being admitted to the epilepsy monitoring unit (EMU) or the ICU for further workup or medication management of their epilepsy. Subject will be eligible for the study if:

1. they have a diagnosis of partial (focal) epilepsy
2. standard of care long- term EEG monitoring is planned
3. during the past 3 days to 1 week prior to EMU admission, have had an average of at least one seizure per day at time of admission to EMU.

Exclusion Criteria:

1. history of unrepaired or palliated congenital cyanotic heart disease

2. history of traumatic head injury to the extent that precludes safe and consistent placement of NIRS-EEG probes.
3. diagnosis of Primary generalized epilepsy
4. Allergy or sensitivity to tape or adhesives
5. Guardian or patient do not give consent/assent to participate in the study
6. Clinical care provider or investigator determines the patient is not appropriate candidate for the study

Contacts and Locations

Go to 

Information from the National Library of Medicine



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): **NCT03054961***

Locations

United States, Wisconsin

The Medical College of Wisconsin
Milwaukee, Wisconsin, United States, 53226

Sponsors and Collaborators


Medical College of Wisconsin

Marquette University

Investigators

Principal Investigator: Harry T Whelan, MD Medical College of Wisconsin

More Information

Go to 

Responsible Party:

Harry T Whelan, MD, Bleser Professor of Neurology, Medical College of Wisconsin

ClinicalTrials.gov Identifier:

[NCT03054961](#) [History of Changes](#)

Other Study ID Numbers:

119371-19

First Posted:

February 16, 2017 Key Record Dates

Last Update Posted:

July 2, 2021

Last Verified:

July 2021

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:

No

Studies a U.S. FDA-regulated Drug Product:

No

Studies a U.S. FDA-regulated Device Product:

Yes

Product Manufactured in and Exported from the U.S.:

No

Keywords provided by Harry T Whelan, MD, Medical College of Wisconsin:

epilepsy

NIRS

cytochrome oxidase redox state

near-infrared spectroscopy

childhood epilepsy

regional cerebral oxygen saturation

partial epilepsy

Additional relevant MeSH terms:

Epilepsy

Epilepsies, Partial

Brain Diseases

Central Nervous System Diseases

Nervous System Diseases