AION BIOSTYEMS, INC. TEMPSHIELD

A prospective, interventional study assessing the effectiveness of the AION BIOSTYEMS, INC. tempshield ("Shield") for continuous temperature monitoring device in the Pediatric Emergency Department.

NCT Number: NCT07145541

Principal Investigator: Sephora Morrison, MD

Sponsor: AION BIOSYSTEMS, INC.

Funded by: AION BIOSYSTEMS, INC.

2 May 2024

CHILDREN'S NATIONAL HOSPITAL

Department of Emergency Medicine
111 Michigan Avenue, NW
Washington, DC 20010
(202) 476-5000

CLINICAL RESEARCH STUDY

INFORMATION SHEET

TITLE OF STUDY: A prospective, interventional study assessing the effectiveness of the AION BIOSYSTEMS, INC. TempShield ("Shield") for continuous temperature monitoring device in the Pediatric Emergency Department

PRINCIPAL INVESTIGATOR: Dr. Sephora Morrison, MD, Emergency Medicine

INTRODUCTION: We are conducting a research project as described below. Fever is the most common reason for children to be brought to an Emergency Department (ED). Early detection and treatment of fever in pediatric patients is important because fever can be a sign of a serious infection or other underlying condition. If left untreated, these infections or conditions can lead to more serious complications, such as organ damage or failure. In this study, we are evaluating the effectiveness of the AION BIOSYSTEMS, INC. TempShield ("the Shield") temperature monitoring device and platform in detecting body temperature for children 2-4 years old.

PROJECT: Your child was identified as an eligible participant because the nurse took your child's temperature. Based on this temperature, your child fit into one of two cohorts of study eligibility: patients whose temperature was either febrile (>37.5 degrees Celsius) or afebrile (<37.5 degrees Celsius). If you consent to participant in this study, we would like to use the AION BIOSYSTEMS, INC. TempShield ("the Shield") temperature monitoring device to monitor your child's temperature for the purpose of research. A member of the research team would attach the temperature monitor to your child's upper chest. Once it's attached it will begin recording their temperature and we ask that they wear the device for a maximum of 7 hours or until discharge from Children's National Hospital Emergency Department if earlier than 7 hours. During the 7 hour period, a research team member will take a manual temperature 4-5 times. At the completion of the study, the adhesive, similar to a band aide, and the device can easily be removed. The device and tablet will be collected by the research team at the end of study procedures, either after 5 oral temperatures or discharge, as well as at the end of research staff hours.

There is a potential clinical benefit that fevers will be detected earlier in subjects wearing the AION BIOSYSTEMS, INC. TempShield and it is hoped that information gained from the study will help assist clinical care workflow and the treatment of future patients. You and your child will be provided a tablet connected to the AION BIOSYSTEMS, INC. device that will display the continuous temperature monitoring throughout your stay. The temperature measurements of this device will not be used for any clinical purpose and should not be taken into account when making any medical decisions. You will receive a $25 gift card after the second oral temperature is obtained. After successfully completing two oral temperatures, the child will receive a stuffed toy. Note that you will not be held responsible for the loss of damage of the AION BIOSYSTEMS, INC. device while it is in your possession.

RISKS/CONFIDENTIALITY: By participating in this study, there is always a potential for a breach of confidentiality. Only the people working on the study will know your name. Researchers will take the necessary steps to prevent this risk from happening by keeping the records of this study confidential.

Additionally, the adhesive tape is silicone-based and hypoallergenic, but there is a small chance that the tape could cause mild skin irritation. Participants with a known allergy or sensitivity to silicone will be excluded from the study for this reason. Should any skin irritation occur the study moderator will instruct the participant to seek medical attention during or after the study. All required FDA biocompatibility testing, and wear length testing has been performed by the manufacturer.

Furthermore, the AION BIOSYSTEMS, INC. TempShield device should not be worn during CT, X-Ray or MRI imaging procedures, as there is a risk of physical harm. Thus, the research team has taken steps to ensure that the device is removed prior to these imaging procedures. These steps include alerting clinical staff to the device's presence and placing a brightly colored wristband on your child's wrist that denotes their participation in this study and the necessary removal of device before the aforementioned imaging procedures.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY:

In 1996 the government passed a law known as The Health Insurance Portability and Accountability Act (HIPAA). This privacy law protects your individually identifiable health information (Protected Health Information or PHI). The privacy law requires you to sign an agreement so researchers can use or share your PHI for research purposes. This describes to you how information about you may be used or shared if you are in a research study. It is important that you read this carefully and ask a member of the research team to explain anything you do not understand.

I authorize the Principal Investigator, Dr. Sephora Morrison and her research staff to create, access, use, and disclose my PHI for the purposes described below.

Protected Health Information that may be used and shared includes:

- Information that identifies you such as name, address, telephone number, date of birth, and other details about you
- Information that relates to your health or medical condition from your medical records
- Laboratory results obtained on specimens collected from you (blood, urine, tissue)
- Questionnaires or surveys you complete
- Interviews conducted with you by members of the research team

- Audio/ video recordings

The Researchers may use and share my Protected Health Information with:

- The Principal Investigator, other Investigators, Study Coordinators, and all administrative staff in charge of doing work for the study
- Government agencies that have the right to see or review your PHI including, but not limited to:
    - The Department of Health and Human Services (DHHS) Office of Human Research Protections (OHRP)
    - The Food and Drug Administration
- Children's National Hospital Institutional Review Board
- Children's National Hospital Institutional Quality Assurance Program
- Other staff in the Human Research Protections Program at Children's National Hospital

VOLUNTARY PARTICIPATION: Your decision to participate or not participate in this research will not affect your current or future care at Children's National.

QUESTIONS: If you have any questions, please call the Principal Investigator, Sephora Morrison, at: 202-476-8877 or 202-924-0557