Preventing Post-Vaccination Presyncope and Syncope in Adolescents Using Simple, Clinic-based Interventions

NCT: NCT04772755

Date: 1/20/2022

Duke University Health System

Consent to Participate in a Research Study
Preventing Post-Vaccination Presyncope and Syncope in Adolescents Using Simple, Clinic-based Interventions

CONCISE SUMMARY

This is a research study to test a strategy designed to prevent fainting (syncope) or symptoms that might occur before fainting (presyncope) in adolescents 10 through 14 years of age who are receiving at least one injected vaccine.

Adolescents in this study will be randomly assigned (like flipping a coin) to one of two groups. Adolescents in Group 1 will select an electronic game to play and have a vibrating cooling device (like a small ice pack) named Buzzy® placed on the arm/s where they will receive their shot/s. Adolescents in Group 2 will receive usual care. They will not choose and play an electronic game and Buzzy will not be applied on the upper arm at the time of vaccination. Adolescents will answer questions about whether they have a fear of needles, if they have anxiety before or after the vaccine injection, how they feel after vaccination, if they have pain from the needles. Adolescents will also be asked about their vaccination experience, and those in Group 1 will be asked about the electronic game and Buzzy.

Only minor risks are expected from this study. Your child may feel slight discomfort from the vibration and coolness of the Buzzy®. Your children may also experience some uneasiness answering some of the questions.

If you are interested in learning more about this study, please continue reading below.

We are asking you to allow your child to take part in a research study because they are scheduled to have a routine vaccine. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. Please ask the study doctor or study staff to explain anything that you do not clearly understand. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if your child is taking part in another research study.

Dr. Emmanuel Walter will conduct the study and it is being funded by the Centers for Disease Control and Prevention (CDC). The sponsor of this study, the CDC, will pay Duke University to perform this research, and these funds may pay part of Dr. Walter's salary.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to have your child participate, Dr. Walter will be your child's doctor for the study. He will be in contact with your child's regular health care provider while your child is in the study and afterwards, if needed.

Duke University Health System

Consent to Participate in a Research Study
Preventing Post-Vaccination Presyncope and Syncope in Adolescents Using Simple, Clinic-based Interventions

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to see how well a strategy designed to prevent fainting or symptoms related to fainting following vaccination works in children 10 through 14 years of age who are receiving one or more injected vaccines. Our strategy is to apply a cold, vibrating device named Buzzy® on their arm/s where they are getting their shot/s just prior to and during the shot/s. If your child is in this group, they will also play an electronic game for 5 minutes prior to, during and after their shot/s. In this study, we will look at whether applying Buzzy® on the arm and playing an electronic game versus usual care makes people feel better during and after receiving vaccinations. Those receiving Buzzy® and the game will have Buzzy® applied to the arm for 30-60 seconds prior to vaccination and during the vaccination. The electronic game will be played for about 5 minutes before vaccination, during vaccination, and for a minimum of 1 minute and up to 15 minutes following vaccination.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 340 children will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?

If you agree for your child to be in this study, you will be asked to sign and date this consent form. Your child must also agree to participate in the study. We will also ask your child if he/she agrees to participate, and if 12 years or older, we will ask him/her to sign this form.

A member of the study staff will ask you questions regarding your child's health (including medical history and current medications). The medical history is obtained to make sure that your child is healthy and is eligible to participate. If your child is not eligible, he/she will not be enrolled, and no further procedures will be done.

Your child will be randomly assigned (like flipping a coin) to one of 2 groups:

Group	Strategy	What is involved
1	Buzzy® + electronic game	Wear Buzzy® on arm just prior to and during shot/s and play an electronic game 3-5 minutes prior to, during, and 1-15 minutes after vaccination
2	Control	This intervention group will receive usual care during vaccination.

Your child will have an equal chance of being assigned to each of the groups. Regardless of which group your child is assigned to, he/she will receive the usual standard of care for vaccinations, including monitoring for about 20 minutes after being vaccinated.

FOR ALL PARTICIPANTS:

All participants will be asked about their medical history, current health status, recent sleep, and about the last time they ate or drank. We will also ask questions about fear of shots, pain, and anxiety. In

Duke University Health System

Consent to Participate in a Research Study
Preventing Post-Vaccination Presyncope and Syncope in Adolescents Using Simple, Clinic-based Interventions

addition, we will measure temperature, weight, height, pulse rate and blood pressure if not already measured by the clinic staff before receiving shots. All subjects will be monitored for about 20 minutes after the vaccination, also called the wait period. Your child will also be provided with the CDC's Advisory Committee on Immunization Practices guidance that they may choose to sit or lie down during the post-vaccination wait period.

FOR PARTICIPANTS ASSIGNED TO THE BUZZY® + ELECTRONIC GAME GROUP:
In addition to the activities that occur for all participants, those who are assigned to the Buzzy® + electronic game group will be asked to play an electronic game on an iPad provided by the study team. They will play the electronic game for 3 to 5 minutes prior to vaccination, during their vaccination, and for 1-15 minutes following vaccination. Buzzy® will be applied on their upper arm/s near the area where they will get their shot/s for 30-60 seconds prior to getting their shots. Buzzy® will be moved further up on their upper arm during the actual vaccine injection. If getting shots in both arms, Buzzy® will be applied on both upper arms before and during the injection.

HOW LONG WILL MY CHILD BE IN THIS STUDY?
If you agree for your child to take part in this study, your child's involvement may last for up to two hours.

You can choose to have your child stop participating at any time without penalty or loss of any benefits to which you or your child are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your study doctor first.

WHAT ARE THE RISKS OF THE STUDY?
Your child is receiving vaccinations today as part of their routine care and not as a part of this study. Your child's health care provider will explain the risks related to the vaccines to you before your child is vaccinated.

As a result of your child participating in this study, they are at risk for the following side effects. You should discuss these with the study doctor and your child's regular health care provider if you choose. There may be some temporary discomfort associated with wearing Buzzy® on the arm as it applies a cold sensation, like wearing an ice pack, and vibrations to the arm. There are few known risks to interacting with an age-appropriate electronic game, and these may include fatigue or boredom.

Your child may also experience some uneasiness from answering some of the questions. These questions will be asked verbally by study staff or in a written format.

There is also the potential risk of loss of confidentiality about information obtained as part of this study. Please see below for additional information regarding confidentiality.

There may be risks, discomforts, or side effects that are not yet known.

Duke University Health System

Consent to Participate in a Research Study
Preventing Post-Vaccination Presyncope and Syncope in Adolescents Using Simple, Clinic-based Interventions

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
There might be no direct benefit to your child for participating in this study, especially if your child is randomized to the usual care group. However, it is possible that participation in this study could decrease your child's chance of fainting or feeling faint after vaccination. There is also a possible benefit of decreased pain associated with vaccination due to the cold and vibration mechanism of Buzzy®. We hope that in the future the information learned from this study will benefit other children.

WILL MY CHILD'S INFORMATION BE KEPT CONFIDENTIAL?
Participation in research may involve some loss of privacy. We will do our best to make sure that information about your child is kept confidential, but we cannot guarantee total confidentiality. Your child's personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. If questionnaires suggest that your child is having considerable anxiety, we will inform your child's health care provider. Your child's personal information may also be given out if required by law.

As part of the study, results of your child's study-related procedures may be reported to CDC and its affiliates. In addition, your child's records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of the CDC, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your child's research record, they may also need to review your child's entire medical record.

The study results will be retained in your child's research record for six years after the study is completed, or until your child reaches the age of 21, whichever is longer. At that time, either the research information not already in your child's medical record will be destroyed or information identifying your child will be removed from such study results at DUHS. Any research information in your child's medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your child's name or other personal information will not be revealed. If the results from this study are published, you may receive notification of this by letter.

Some people or groups who receive your child's health information might not have to follow the same privacy rules. Once your child's information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share your child's private information with anyone not involved in the

Duke University Health System

Consent to Participate in a Research Study
Preventing Post-Vaccination Presyncope and Syncope in Adolescents Using Simple, Clinic-based Interventions

study, the federal law designed to protect your child's health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

This study is supported by the Centers for Disease Control and Prevention (CDC). Because of this support, your study information is protected by a Certificate of Confidentiality.

With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.
Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

WHAT ARE THE COSTS TO YOU?
You or your insurance provider will be responsible and billed for all costs related to your child's routine medical care, including copayments and deductibles. Routine medical care services are those that your child would have received for his/her condition if he/she were not participating in this research study.

WHAT ABOUT COMPENSATION?
You will be reimbursed with a $40 ClinCard for your expenses related to your child's participation (parking, gas, and time).

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that your child is injured as a result of his/her participation in this research study. However, there is no

Duke University Health System

Consent to Participate in a Research Study
Preventing Post-Vaccination Presyncope and Syncope in Adolescents Using Simple, Clinic-based Interventions

commitment by Duke University, Duke University Health System, Inc., or your child's Duke physicians to provide monetary compensation or free medical care to your child in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Walter using the pager number at (919) 970-5720 during regular business hours, after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

Your decision to allow your child to be in this study is voluntary. You may choose not to have your child be in this study, or, if you agree to allow your child to be in the study, you may withdraw your child from the study at any time. If your child withdraws from the study, no new data about your child will be collected for study purposes unless the data concerns an adverse event (a bad effect) related to the study.

If such an adverse event occurs, we may need to review your child's entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor. We may want to have an investigator assess your child.

Your decision for your child not to participate or to withdraw your child from the study will not involve any penalty or loss of benefits to which he/she are entitled, and will not affect their access to health care at Duke. Your child can still get vaccinated today, regardless of whether or not you agree to participate in the study. If you decide to withdraw your child from the study, we ask that you notify any member of the study team during the visit or you can contact Dr. Walter in writing and let him know that your child is withdrawing from the study. His mailing address is Duke Vaccine and Trials Unit, 2608 Erwin Road, Suite 210, Durham, NC 27705.

The study doctor or sponsor may withdraw your child from this study for any reason at any time even without your consent. This could occur, for example, if the study doctor decides that it is in your child's best interest.

We will tell you about new information that may affect your child's health, welfare, or willingness to stay in this study.

A description of this clinical trial will be available on https://www.clinicaltrials.gov/ as required by U.S. Law. This Web site will not include information that can identify you or your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Duke University Health System

Consent to Participate in a Research Study
Preventing Post-Vaccination Presyncope and Syncope in Adolescents Using Simple, Clinic-based Interventions

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Emmanuel Walter using the 24 hour pager number at (919) 970-5720.

For questions about you and your child's rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to my child and me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree for my child to be in this study, with the understanding that I may withdraw my child at any time. I have discussed the study with my child, who agrees to be in the study. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Parent or Legal Guardian	Date	Time
_____	_____	_____
Signature of Subject (if 12 years or older)	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time