A randomized controlled trial comparing cosmetic outcomes of pediatric laceration closure using a tissue adhesive (Dermabond™) versus adhesive strips (Steri-Strips™) versus absorbable sutures

Consent Form

NCT ID: NCT03280628

Date: 6/3/2019

Principal Investigator:
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Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Maureen Saint Georges Chaumet, MD, MS **Revision Date: 8/10/2017**
Study Title: A randomized controlled trial comparing cosmetic outcomes of pediatric laceration closure using a tissue adhesive (Dermabond™) versus adhesive strips (Steri-Strips™) versus absorbable sutures
Institution/Hospital: Vanderbilt Children's Hospital
This informed consent applies to a parent or legal guardian.

Name of participant:_____Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

1. **What is the purpose of this study?**

   You are being asked to take part in this research study because your child has a skin cut that needs to be closed. There are several methods of closing a skin cut: stitches, skin glue, and medical tape. Stitches have been used for a long time to close skin cuts. Skin glue (invented in the 1970s) and medical tape (invented in the 1960s) are two newer methods to close skin cuts. The purpose of this study is to find out which method (stitches, skin glue, or medical tape) of closing skin cuts results in the least amount of scarring. Other things we will be looking at are which method is the cheapest, which causes the least pain, which requires the least amount of sedation and which patients and parents like the best.

2. **What will happen and how long will you be in the study?**

   If your child participates in this study, his/her skin cut will be closed using one of three methods: stitches, skin glue, or medical tape. The method used will be randomly picked. It is a lot like flipping a coin, except that it is done by a computer to make sure that there are about the same number of people on each treatment plan of the study. We will then ask you and your child to answer a short questionnaire about your experience in the Emergency Room. We will also have you rate the appearance of 3 random scars. About 3 months after your visit, we will ask you to take a picture of your child's scar and send us the picture by e-mail. We will ask you to rate your child's scar at that time. If you prefer, you can instead come by the Emergency Room at Vanderbilt with your child at a time that is convenient for you about 3 months after your initial visit and we will take a picture of your child's scar. During the study, we will review your child's medical record and billing information.

3. **Costs to you if you take part in this study:**

   If you agree to take part in this research study, you are responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.
   You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

4. **Side effects and risks that you can expect if you take part in this study:**

It is unlikely that your child would have any side effects from participating in this study. All children who have a cut of their skin that needs to be repaired have a risk of infection and bleeding. Your risk is not increased because of this study.

5. Risks that are not known:

Skin glue (Dermabond), medical tape (Steri-Strips) and stitches are all methods of closing skin cuts that are approved by the Food and Drug Administration (FDA). Thus, there are no risks that we do not know about at this time.

6. Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study: The goal of this study is to figure out which method used to close skin cuts in children is best in regards to resulting scar, length of ER stay, and pain associated with the closure of a skin cut.

b) The benefits you might get from being in this study: Whether you allow your child to participate in this study or not, your child's skin cut will be closed. Thus, we do not expect this study to benefit your child in any additional way.

8. Other treatments you could get if you decide not to be in this study:

Regardless of whether you decide to be in this study or not, your child's skin cut will most likely be repaired using sutures, skin glue, or medical tape.

9. Payments for your time spent taking part in this study or expenses:

You will be compensated with a $15 check for your time after sending in a picture of your child's scar at 3 months or coming in to the Emergency Room at Vanderbilt to have a picture of your child's scar taken at 3 months.

10. Reasons why the study doctor may take you out of this study:

If your child develops signs of an allergy to the sutures, skin glue or medical tape, he or she may be taken out of the study.

11. What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor by contacting her at the phone number or email below. Deciding to not be part of the study will not change your regular medical care in any way.

12. Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please contact Dr. **Maureen Saint Georges Chaumet** at **(615) 835-1809 (Pager) or LacerationResearchStudy@vanderbilt.edu.**

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Confidentiality:

If your child takes part in this study, we will make every effort to keep his or her information confidential.

We will store all of your child's research records in locked cabinets and secure computer files. We will not put your child's name on any research data. Instead, we will label your child's information with a study number. The master list that links a person's name to their study number is stored in a locked cabinet or on a secure computer file.

If results of this research are published, we would not use information that identifies your child. If a photo of your child's scar is published, we will make every effort to block identifying features, for example, placing a black rectangle over the eyes if they appear in the photo.

We would only use your child's information for research. These are some reasons that we may need to share the information you or your child give us with others:

- If it's required by law.
- If we think your child or someone else could be harmed.

14. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Maureen Saint Georges Chaumet and her study team may share the results of your study-linked questionnaires and photos, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, and insurance companies for billing purposes. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

Dr. Maureen Saint Georges Chaumet or Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Maureen Saint Georges Chaumet and her staff will keep your PHI in strict confidence, and will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Maureen Saint Georges Chaumet in writing and let her know that you withdraw your consent. Her mailing address is Vanderbilt University Medical Center, Pediatric Emergency Medicine, 2200 Children's Way, Nashville, TN 37232-9100. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PARENT OR LEGAL GUARDIAN AGREEING TO LET THEIR CHILD PARTICIPATE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to let my child take part in this study.

Date	Signature of Parent or Legal Guardian	
	Printed Name of Parent or Legal Guardian	Time

Consent obtained by:

Date	Signature	
	Printed Name and Title	Time