



HRP-591 - Protocol for Human Subject Research

Protocol Title:

A randomized controlled study of efficacy of infrared vein visualization versus standard technique

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Important Instructions for Using This Protocol Template:

1. Add this completed protocol template to your study in CATS IRB (<http://irb.psu.edu>) on the "Basic Information" page, item 7.
2. This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB to determine whether a study meets all applicable criteria for approval.
3. **Type your protocol responses below the gray instructional boxes of guidance language. If the section or item is not applicable, indicate not applicable.**
4. **For research being conducted at Penn State Hershey or by Penn State Hershey researchers only, delete the instructional boxes from the final version of the protocol prior to upload to CATS IRB (<http://irb.psu.edu>). For all other research, do not delete the instructional boxes from the final version of the protocol.**
5. When making revisions to this protocol as requested by the IRB, please follow the instructions outlined in the Study Submission Guide available in the Help Center in CATS IRB (<http://irb.psu.edu>) for using track changes.

If you need help...

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1.0 Objectives

1.1 Study Objectives

Assess the efficacy of the vein visualization device AccuVein (AccuVein, Inc., Huntington, NY) in comparison to a standard technique for establishing intravenous (IV) access in the infant population (<2 years old)

1.2 Primary Study Endpoints

Success Rate of IV Insertion within three allowed attempts

1.3 Secondary Study Endpoints

Total number of attempts and time to successful insertion

2.0 Background

2.1 Scientific Background and Gaps

Children undergoing anesthesia procedures need intravenous access. This may be done after anesthesia induction in infants. This may be challenging in the infant population under anesthesia when establishing IV access rapidly is paramount, as emergency drugs may need to be administered if a complication were to occur at induction. The infant population is especially challenging in this regard due to increased body fat.

2.2 Previous Data

The success rate at first attempt IV induction in children varies from 32 – 92% depending on provider experience. Various techniques have been tried in the past that include application of warming devices and use of ultrasound. Recent literature suggests use of infrared illumination to aid vein visualization, with a device such as the AccuVein (AccuVein, Inc., Huntington, NY), has been successfully used.

2.3 Study Rationale

There are few reports of use of the AccuVein device in the infant population. Our experience with this device in infant population has been positive. Additionally, we think that this will be a good learning tool for residents to help identify a target vein for IV access.

3.0 Inclusion and Exclusion Criteria

3.1 Inclusion Criteria

1. Age: birth to <2years of age
2. Sex: male or female
3. Undergoing anesthesia procedures at Penn State Health, Hershey Medical Center and Penn State Children's Hospital
4. ASA physical status 1,2 or 3
5. Parent/guardian fluent in written and spoken English

3.2 Exclusion Criteria

1. Age: ≥ 2 years of age
2. Emergency procedures requiring anesthesia

2. ASA physical status 4
3. Patients with pre-existing IV access (IV access in situ)

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

1. Withdrawal of parental permission
2. Child develops significant laryngospasm that needs intervention with succinylcholine

3.3.2 Follow-up for withdrawn subjects

Not applicable

4.0 Recruitment Methods

4.1 Identification of subjects

Potential subjects will be identified from the electronic operating room scheduling system (surginet) by reviewing the operative list schedule the day before or on the day of their scheduled surgical or diagnostic procedure.

4.2 Recruitment process

Not applicable

4.3 Recruitment materials

Not applicable

4.4 Eligibility/screening of subjects

Not applicable

5.0 Consent Process and Documentation

5.1 Consent Process

5.1.1 Obtaining Informed Consent

5.1.1.1 Timing and Location of Consent

The parental permission for research will be obtained on the day of the procedure during the pre-anesthesia evaluation.

5.1.1.2 Coercion or Undue Influence during Consent

Parents and legal guardians of patients that are enrolling in the study will be told that participation is voluntary and will not in any way compromise the standard of care that the patient will receive.

5.1.2 Waiver or alteration of the informed consent requirement

We are requesting a partial waiver of consent for recruitment to screen medical record information to identify subjects meeting the inclusion/exclusion criteria.

5.2 Consent Documentation

5.2.1 Written Documentation of Consent

Written parental permission for participation in the study will be obtained. An original will be given to the parent/guardian for their records and another original will be kept by the research team. A copy will be uploaded to their medical record.

5.2.2 Waiver of Documentation of Consent (Implied consent, Verbal consent, etc.)

N/A

5.3 Consent – Other Considerations

5.3.1 Non-English Speaking Subjects

N/A

5.3.2 Cognitively Impaired Adults

5.3.2.1 Capability of Providing Consent

N/A

5.3.2.2 Adults Unable To Consent

N/A

5.3.2.3 Assent of Adults Unable to Consent

N/A

5.3.3 Subjects who are not yet adults (infants, children, teenagers)

5.3.3.1 Parental Permission

Parent or legal guardian will give consent

5.3.3.2 Assent of subjects who are not yet adults

Assent will not be obtained. The capability of these children (taking into account the ages, maturity, and psychological state of the children involved) is so limited that they cannot reasonably be consulted.

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

- ☐ Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study. *[Mark all parts of sections 6.2 and 6.3 as not applicable]*
- ☒ Authorization will be obtained and documented as part of the consent process. *[If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]*
- ☒ Partial waiver is requested for recruitment purposes only (Check this box if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained). *[Complete all parts of sections 6.2 and 6.3]*
- ☐ Full waiver is requested for entire research study (e.g., medical record review studies). *[Complete all parts of sections 6.2 and 6.3]*
- ☐ Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained). *[Complete all parts of sections 6.2 and 6.3]*

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

6.2.1.1 Plan to protect PHI from improper use or disclosure

Information is included in the “Confidentiality, Privacy and Data Management” section of this protocol.

6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers

Identifiers will be destroyed at the completion of the study.

6.2.2 Explanation for why the research could not practicably be conducted without access to and use of PHI

Information must be obtained from the subject’s electronic medical record during recruitment to determine eligibility and, in some cases, to confirm information discussed with the subject’s parent/guardian in regards to their medical history.

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

The waiver is requested only for recruitment to determine subject eligibility to ensure that no medical conditions that fall into the exclusion criteria are present and would thus preclude enrollment. This waiver will minimize the enrollment of subjects’ who may ultimately fail to meet the study inclusion/exclusion criteria.

6.3 Waiver or alteration of authorization statements of agreement

Protected health information obtained as part of this research will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other permitted uses and disclosures according to federal regulations.

The research team will collect only information essential to the study and in accord with the ‘Minimum Necessary’ standard (information reasonably necessary to accomplish the objectives of the research) per federal regulations.

Access to the information will be limited, to the greatest extent possible, within the research team. All disclosures or releases of identifiable information granted under this waiver will be accounted for and documented.

7.0 Study Design and Procedures

7.1 Study Design

This will be a randomized controlled study.

The objective of the study is to assess the efficacy of the vein visualization device in comparison to a standard technique in the infant population (<2years). Subjects will be randomized to the vein visualization or standard group using a computer generated randomization program.

7.2 Study Procedures

7.2.1 Day of Surgery

After obtaining informed consent, the infant will be randomized to the vein visualization or standard group based on a computer generated number.

Standard anesthesia induction procedures will be used. This includes application of standard ASA monitoring at induction and standard inhalation induction with sevoflurane.

Once the subject is deemed ready for intravenous access attempt, a tourniquet will be applied on the corresponding limb where IV access is contemplated.

For those randomized to the control group (standard technique group), the standard technique for establishing IV access will be used. The standard technique involves directly identifying the vein after application of a tourniquet, cleaning with alcohol and then siting the intravenous catheter.

For those randomized to the vein visualization group, the AccuVein device will be used as an aid to identify the vein after application of a tourniquet. The technique of actual insertion of the intravenous catheter will be the same as the standard technique. The device will be used to better visualize and identify the vein.

If, after 3 needle sticks, IV access has not been established using the technique for the group to which the subject was assigned (standard or vein finder), the care provider will use the other technique (standard or vein finder) to attempt to insert the IV line.

In order to avoid operator variation, the intravenous catheter will be inserted by an experienced pediatric anesthesiologist who is a member of the research team. Currently all the pediatric anesthesia faculty members are familiar with, and have used, the vein finder in case of difficult intravenous access. If a complication develops while attempting to start an IV using the vein finder or standard technique, and a rapid IV access is needed, it will be at the attending anesthesiologist's discretion to perform the IV rapidly with either technique, since our faculty anesthesiologists are proficient with both techniques. Multiple anesthesiologists may attempt the IV simultaneously. This is how we would normally manage this situation and is the standard of care. If this happens we will withdraw the child from the study.

Data to be collected:

The time to successful IV insertion will be from the first time that the canula touches the skin to until successful IV access; up to 3 attempts. After the 3rd attempt, if still unsuccessful, the alternative technique will be used as rescue. Again, time to successful insertion will be noted. Success at IV will be determined by flushability with 5 ml of sterile normal saline. The site(s) of access will also be recorded.

Medical Record Information: This information will include, but is not limited to: Age, gender, physical status, weight, height, skin color, surgical procedure, presenting underlying conditions and co-morbidities.

7.3 Duration of Participation

Patient participation will end at the end of surgery.

8.0 Subject Numbers and Statistical Plan

8.1 Number of Subjects

A sample size of 160 patients to include a 15% margin above the number indicated by the sample size determination, to allow for subject withdrawal or situations of incomplete subject data.

8.2 Sample size determination

Assuming 90% success rate with the vein visualization device and 95% confidence level, a sample size of 139 patients would be needed to be enrolled in the study.

8.3 Statistical methods

Sigmastat software will be used for statistical analysis. A p-value<0.05 will be considered significant. For statistical analysis, a chi square test will be used for comparing data on attempts and ANOVA for comparing data on times.

9.0 Confidentiality, Privacy and Data Management

See the Research Data Plan Review Form

10.0 Data and Safety Monitoring Plan

11.0 Risks

Loss of confidentiality is a potential risk when conducting human subject search.

Increase in the number of IV access attempts and/or time to successful IV placement.

12.0 Potential Benefits to Subjects and Others

12.1 Potential Benefits to Subjects

If you are assigned to the vein visualization group, it is possible that the insertion of your IV access line may take less time or need fewer needle sticks, but this is not guaranteed.

12.2 Potential Benefits to Others

This study should provide evidence of whether the AccuVein vein visualization device can decrease the number of attempts or the time to successful IV insertion in the infant population.

13.0 Sharing Results with Subjects

N/A

14.0 Subject Stipend (Compensation) and/or Travel Reimbursements

N/A

15.0 Economic Burden to Subjects

15.1 Costs

N/A

- 15.2 Compensation for research-related injury**
N/A

16.0 Resources Available

- 16.1 Facilities and locations**
Penn State Health, Hershey Medical Center and Penn State Children's Hospital
- 16.2 Feasibility of recruiting the required number of subjects**
We perform anesthesia on approximately 9000 children a year and, of these, at least 1000 children belong to the infant age group. Of these 10-20% may have preexisting IV so about 600-800 children will fit the criteria for potential inclusion in the study.
- 16.3 PI Time devoted to conducting the research**
Dr. Dalal is assigned to the children's hospital as part of her normal rotation. Dr. Dalal is a pediatric anesthesiologist. 70% of her practice includes children.
Dr. Dalal, will have four academic days each month.
- 16.4 Availability of medical or psychological resources**
N/A
- 16.5 Process for informing Study Team**
Meetings will be held periodically as needed to ensure all research team members are informed about the protocol and their duties. Team emails will also be used to keep team members updated.

17.0 Other Approvals

- 17.1 Other Approvals from External Entities**
N/A

17.2 Internal PSU Committee Approvals

Check all that apply:

- ☐ Anatomic Pathology – Hershey only – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of HRP-902 - Human Tissue For Research Form on the "Supporting Documents" page in CATS IRB. This form is available in the CATS IRB Library.
- ☐ Animal Care and Use – All campuses – Human research involves animals and humans or the use of human tissues in animals
- ☐ Biosafety – All campuses – Research involves biohazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy).
- ☐ Clinical Laboratories – Hershey only – Collection, processing and/or storage of extra tubes of body fluid specimens for research purposes by the Clinical Laboratories; and/or use of body fluids that had been collected for clinical purposes, but are no longer needed for clinical use. Upload a copy of HRP-901 - Human Body Fluids for Research Form on the "Supporting Documents" page in CATS IRB. This form is available in the CATS IRB Library.

- ☐ Clinical Research Center (CRC) Advisory Committee – All campuses – Research involves the use of CRC services in any way.
- ☐ Conflict of Interest Review – All campuses – Research has one or more of study team members indicated as having a financial interest.
- ☐ Radiation Safety – Hershey only – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload a copy of HRP-903 - Radiation Review Form on the “Supporting Documents” page in CATS IRB. This form is available in the CATS IRB Library.
- ☐ IND/IDE Audit – All campuses – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.
- ☒ Scientific Review – Hershey only – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review requirement may be fulfilled by one of the following: (1) external peer-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center Advisory committee. NOTE: Review by the Penn State Hershey Cancer Institute Scientific Review Committee is required if the study involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website at: <http://www.pennstatehershey.org/web/irb/home/resources/investigator>

18.0 Multi-Site Research

18.1

N/A

19.0 Adverse Event Reporting

19.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

20.0 Study Monitoring, Auditing and Inspecting

20.1 Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

21.0 Future Undetermined Research: Data and Specimen Banking

N/A

22.0 References

1. Kaddoum et al. A randomized controlled trial comparingPediatric Anesthesia 22 (2012) 884–889
2. Rothbart et al. BMC Res Notes (2015) 8:463
3. De Graaf et al. Near infra-red light to aid peripheral iv cannulation.....Anaesthesia 2013, 68, 835–845
4. Nafiu OO, Burke C, Cowan A et al. Comparing peripheral venous access between obese and normal weight children. Pediatr Anesth 2010; 20: 172–176.
5. Jacobson AF, Winslow EH. Variables influencing intravenous catheter insertion difficulty and failure: an analysis of 339 intravenous catheter insertions. Heart Lung 2005; 34: 345–359.
6. Yen K, Riegert A, Gorelick MH. Derivation of the DIVA score: a clinical prediction rule for the identification of children with difficult intravenous access. Pediatr Emerg Care 2008; 24: 143–147.