PARTICIPANT INFORMATION SHEET AND CONSENT FORM

The Pediatric Fast Fluid Trial 2

Rapid pediatric fluid resuscitation: a randomized controlled trial comparing the efficiency of two provider-endorsed manual fluid resuscitation techniques.

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1. **Regional Medical Associates Research Scholarship (G. Harvey)**
2. **CIHR Health Professional Student Research Award (E. Cole)**
3. **HHS Early Research Career Award (M. Parker)**

We are inviting you to participate in a research study examining the practical aspects of fluid resuscitation in children. The trial is exclusive to McMaster Children's Hospital and participants will include health care staff and students.

Choosing to participate in the study is voluntary (your choice). We thank you for taking the time to consider being part of our study.

Introduction
The most recent septic shock guidelines outline the goals for administration of rapid intravenous fluids during resuscitation. These guidelines specify a goal of 20 mL/kg during the first five minutes and up to 60 mL/kg during the first 15 minutes of resuscitation if necessary. A variety of methods exist for the administration of intravenous fluids including manual syringe, pressure bag support, and rapid infusion devices. While pressure bag and rapid infuser devices are typically available in some hospital areas, they may not be immediately available on the ward or other areas where children are resuscitated. The appropriateness of use in young children of the Level-1 Rapid Infuser or similar systems, which administer 1 litre of resuscitation fluid in 1-2 minutes, is also unclear. For pragmatic reasons, the most common methods typically utilized are the manual syringe techniques.

What is the study about?
Our study will examine practical aspects of fluid resuscitation using manual syringe techniques. We seek to establish the best method to provide fluids rapidly to a child when this is medically indicated.

Why are you being asked to take part?
We are asking all health care staff and trainees to consider participating in our trial. We hope to enrol 16 people in our study and your participation will help us meet that goal.

What does the study involve?
This non-clinical study aims to recruit a total of 16 healthcare professionals and trainees as participants from McMaster Children's Hospital. You will be paired with another participant for the purposes of the trial.

On each of two days you will be asked to perform a simulated pediatric fluid resuscitation on a mannequin with an intravenous catheter in place (one as a pair and one alone), using a specific technique. There will be an opportunity to practice before starting the actual trial. The necessary equipment and fluid will be provided to you, and you will be asked to use these to administer a prescribed amount of fluid to the simulated patient. An assistant will time your progress as you administer the resuscitation fluid until you feel you have administered the specified amount. We will also be recording participant trials with a video camera, although the camera will be focussed on the mannequin where the IV fluid is being given in order to not capture any information that could identify you in the video.

When you are done, you will be asked to fill out a short questionnaire regarding your experience during the scenario.

Are there any risks involved?
The risks of this study are minimal. Participants may experience hand cramping from the administration of normal saline by hand via a syringe into the model. While you will be encouraged to provide fluids as fast as possible, as one would during a real resuscitation, you are free to participate at a pace that you deem safe and comfortable. You may cease participation at any point in time should you not feel able to complete the required task.

Are there any benefits?
This research may assist in formulating pragmatic evidence-based recommendations to providers resuscitating children in shock - a common and life threatening pediatric condition.

A $25 Tim Horton's gift certificate will be provided to participants as a token of appreciation for their time. All participants will also be eligible to win an additional prize.

General
If you have any questions about the study please discuss these with Evan Cole, Dr. Harvey, Dr. Parker, or the study coordinator.

If you require more information about the study the study coordinator or one of the investigators will provide this for you.

Information about each participant will only be accessed by those directly involved in the study. No data that could identify an individual participant will be accessible to anyone not directly involved in the study. No published data will identify any individual.

Results of the study will be published in an appropriate journal at completion of the study. Results will also be presented at least one scientific conference. The study outcome will be relayed earlier through internal communications.

This study has been reviewed by the Hamilton Health Sciences/McMaster Faculty of Health Sciences Research Ethics Board (HHS/FHS REB). The REB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call The Office of the Chair, HHS/FHS REB at 905.521.2100 x 42013.

The Fast Fluid Trial Consent Form

I have read and I understand the information sheet dated 02/12/2012 for volunteers taking part in the study designed to assess rapid fluid administration in children. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

I have had the opportunity to ask questions and understand the study.

I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time.

I understand that taking part in this study is confidential and that no material which could identify me will be used in any reports on this study.

I understand the compensation provisions for this study.

I have had time to consider whether to take part.

I know who to contact if I have any questions about the study.

I wish to receive a copy of the results YES / NO

The Fast Fluid Trial Consent Form for Participants

Participant:
I have read the preceding information thoroughly. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I agree to participate in this study. I understand that I will receive a signed copy of this form.

Name	Signature	Date

Person obtaining consent:
I have discussed this study in detail with the participant. I believe the participant understands what is involved in this study.

Name, Role in Study	Signature	Date

Investigator:
In my judgment, this participant has the capacity to give consent, and has done so voluntarily.

Dr. Melissa Parker

Name, MD	Signature	Date