



RESEARCH INFORMATION SHEET

Name of Study: **POND-BP Study**

Who is Eligible: Children aged 6-17 years old with Type 1 Diabetes who attend the Alberta Children's Hospital Diabetes Clinic and without a current diagnosis of high blood pressure or currently taking medications affecting blood pressure

Brief Description: POND-BP is an acronym for **P**ediatric **O**besity (or Type 1 Diabetes) and **N**octurnal **D**ipping of **B**lood **P**ressure. The purpose of this study is to learn about blood pressure patterns during daytime and sleeping. This study involves wearing a blood pressure monitor throughout the day and night for 24 hours.

Want more information or have a question? Call Heidi at 403-8866 or email Heidi.Virtanen@ahs.ca



ASSENT FORM (age 7-14 years)

TITLE: Pediatric Obesity (or Type 1 Diabetes) and Nocturnal Dipping of Blood Pressure (POND-BP): A Prospective Cohort Study

SPONSOR: Alberta Children's Hospital, Department of Pediatrics, Innovation Award

INVESTIGATORS: Dr. Josephine Ho
Dr. Silviu Grisaru

What is a research study?

- A research study is a way to find out new information about something. Children do not need to be in a research study if they don't want to.

Why are you being asked to be part of this research study?

- You are being asked to take part in this research study because we are trying to learn more about blood pressure throughout the day of children in weight management or diabetes clinics. We are asking you to be in the study because you are part of the weight management or diabetes clinic. About 120 children will be in this study.

If you join the study what will happen to you?

We want to tell you about some things that will happen to you if you are in this study.

1. You will be in the study for one year (Baseline visit, Follow-up visit at 1 year)
2. We will take some measurements including height, weight, waist circumference and blood pressure.
3. Information such as lab test results, medications, medical history, and family's health will be collected from your usual clinic visits.
4. We will ask you and your parents to fill out a questionnaire about your health.
5. At both study visits you will go home wearing a blood pressure cuff. This will take measurements of your blood pressure throughout the day and night, for 24 hours.
6. If you are no longer followed in the Pediatric Center for Weight and Health or diabetes clinic, we would like to contact you to organize a follow-up visit and gather information.

Will any part of the study hurt?

We will aim to coordinate any lab tests with your usual clinic lab tests so you do not have to do extra blood work for the study. The blood pressure cuff may be slightly uncomfortable to wear, but it does not hurt.

Will the study help others?

- This study might find out things that will help other children with being healthy someday.

Do your parents know about this study?

- We will talk to your parents about your participation in this study as well. You can talk this over with them before you decide.

Ethics ID: REB17-0520

Study Title: Pediatric Obesity and Nocturnal Dipping of Blood Pressure (POND-BP)

PI: Dr. Josephine Ho 403-955-8866

Version number/date: 1.0 May 4, 2017

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Who will see the information collected about you?

- The information collected about you during this study will be kept safely locked up. Nobody will know it except the people doing the research.
- The study information about you will be part of your usual clinic visits, so your parents and usual clinic staff will know. The researchers will not tell your friends or anyone else.

What do you get for being in the study?

- Your family will get a parking voucher for each visit (\$10) and when you return the blood pressure machine at each visit you will get a Chapters gift card for \$10 (maximum of \$20).

Do you have to be in the study?

- You do not have to be in the study. No one will be upset if you don't want to do this study. If you don't want to be in this study, you just have to tell us. It's up to you.
- You can also take more time to think about being in the study.

What if you have any questions?

- You can ask any questions that you may have about the study. If you have a question later that you didn't think of now, either you can call or have your parents call 403-955-8866 Dr. Josephine Ho.
- You can also take more time to think about being in the study and also talk some more with your parents about being in the study.

What choices do you have if you say no to this study?

- This study is extra, so if you don't want to do it nothing else will change about your usual clinic visits.

Other information about the study.

- If you decide to be in the study, please write your name below.
- You can change your mind and stop being part of it at any time or ask researchers not to use the information they collected from you for the study. All you have to do is tell the person in charge. It's okay. The researchers and your parents won't be upset.
- You will be given a copy of this paper to keep

Would you like to take part in this study?

_____ Yes, I will be in this research study. _____ No, I don't want to do this.

Child's name	Signature of the child	Date

Person obtaining assent	Signature	Date

Ethics ID: REB17-0520

Study Title: Pediatric Obesity (or Type 1 Diabetes) and Nocturnal Dipping of Blood Pressure (POND-BP)

PI: Dr. Josephine Ho 403-955-8866

Version number/date: 2.0 Oct 18, 2018



CONSENT FORM (guardians and youth older than 14 years)

TITLE: Pediatric Obesity (or Type 1 Diabetes) and Nocturnal Dipping of Blood Pressure (POND-BP): A Prospective Cohort Study

SPONSOR: Alberta Children's Hospital, Department of Pediatrics, Innovation Award

INVESTIGATORS: Dr. Josephine Ho
Dr. Silviu Grisaru

This consent form is only part of the process of informed consent. When we refer to "you" we mean you, or your child being followed by our clinic. It should give you the basic idea of what the research is about and what your child's participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form.

BACKGROUND

Blood pressure abnormalities contribute to higher risk of cardiovascular disease in adults. Clinic blood pressure measurements may over or under estimate high blood pressure, or miss blood pressure abnormalities which occur at other times during the day. Normally, we would expect to see a drop or "dip" in blood pressure during sleep. "Dipping" of blood pressure during sleep can be detected by 24 hour blood pressure monitoring but not by clinic measurements. With 24 hour blood pressure monitoring, we can see the pattern of blood pressure over the day and night and be able to detect abnormalities (examples: high blood pressure or "non-dipping" of blood pressure at night). Sometimes abnormalities in blood pressure are detected by 24 hour monitoring despite normal blood pressure values in clinic. The aim of this study is to determine the prevalence of "non-dipping" and masked hypertension (high blood pressure) in pediatric patients attending the weight management clinic or diabetes clinic.

WHAT IS THE PURPOSE OF THE STUDY?

The objectives of this study are:

1. To determine the prevalence of non-dipping and masked hypertension on 24 hour ambulatory blood pressure monitoring in pediatric patients presenting to a weight management clinic or diabetes clinic.
2. To look at associations between non-dipping or masked hypertension and markers of metabolic syndrome (e.g. waist circumference, lipids, glucose, insulin) or glycemic control (HbA1c).
3. To assess if 1 year follow-up in the weight management program or diabetes clinic is associated with changes in prevalence of non-dipping and masked hypertension.

WHAT WOULD MY CHILD HAVE TO DO?

This study will be coordinated with your child's usual standard of care clinical visits and lab tests through the Pediatric Center for Weight and Health or Diabetes Clinic. Information collected includes:

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Measurements: height, weight, waist circumference, blood pressure

Lab tests: sugar, cholesterol, liver test, kidney tests or HbA1c (note that extra blood tests will not be done for this study, but this information will be collected from your child's clinic charts)

Questionnaires: gender, date of birth, birth weight, medications, allergies, symptoms, past medical history, family medical history

24 hour blood pressure monitoring: at both baseline and 1 year follow-up visits, a blood pressure cuff will be placed on your child's arm that is attached to a small, portable machine that measures blood pressure once every 20 minutes for an entire day and once an hour at nighttime.

There will be:

Baseline visit: conducted before or after a regular scheduled clinic appointment (at your convenience).

Follow-up visit: will be conducted 1 year after the baseline visit for this study

If your child is no longer followed in the Pediatric Center for Weight and Health clinic or Diabetes clinic, you will be contacted by the research team to return for the follow-up study visit. We would like to communicate with you by telephone, email and/or postal service – depending on your preference.

WHAT ARE THE RISKS?

There are no risks to participating in this study since the data collected will be in the form of questionnaires and also information collected from usual standard clinic visits. 24 hour blood pressure monitoring may be slightly uncomfortable while wearing the blood pressure cuff.

ARE THERE ANY BENEFITS FOR MY CHILD?

If you agree for your child to participate in this study there may or may not be a direct medical benefit to them. The information we get from this study may help us to provide better treatments in the future for patients in weight management programs or with Type 1 Diabetes. If abnormal results are found from the 24 hour blood pressure monitoring, participants will be referred to cardiology and nephrology for further evaluation as per usual standard of care.

DOES MY CHILD HAVE TO PARTICIPATE?

Participation in this study is voluntary and your child may withdraw from it at any time without jeopardizing their health care. If you and your child would like to withdraw your child or their data from the study then please inform the research coordinator or Dr. Josephine Ho. The research team may also withdraw your child from the study. If new information becomes available that might affect your child's willingness to participate in the study, you will be informed as soon as possible.

WHAT ELSE DOES MY CHILD'S PARTICIPATION INVOLVE?

There is nothing else involved in this study.

WILL WE BE PAID FOR PARTICIPATING, OR DO WE HAVE TO PAY FOR ANYTHING?

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Your family will be provided with a parking voucher for each research visit. After the 24 hour blood pressure monitor is returned at each the baseline and 1 year follow-up visit, your child will receive a Chapters gift card for \$10 (\$20 total).

WILL MY CHILD'S RECORDS BE KEPT PRIVATE?

Results from the 24 hour blood pressure monitoring for this study will be added to your medical record at the Alberta Children's Hospital. A letter summarizing your results will be given to your usual doctor in the Pediatric Centre for Weight and Health or Diabetes Clinic. Only your Alberta Health Services healthcare professionals would have access to your medical chart for the purpose of providing complete care and acting on abnormal results. Other information gathered on you will be kept confidential with none of the information being released without your expressed written consent. Only the local research team will have access to identifying information. It will be stored in a locked office at the Alberta Children's Hospital. Your child will be assigned a study identification number and any results will be presented in group form. The University of Calgary Conjoint Health Research Ethics Board will have access to the records.

IF MY CHILD SUFFERS A RESEARCH-RELATED INJURY, WILL WE BE COMPENSATED?

In the event that your child suffers injury as a result of participating in this research, no compensation will be provided to you by the University of Calgary, the Alberta Health Services or the Researchers. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your child's participation in the research project and agree to their participation as a subject. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw your child from the study at any time without jeopardizing their health care. If you have further questions concerning matters related to this research, please contact:

Dr. Josephine Ho (403) 955-8866

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair of the Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

Parent/Guardian's Name

Signature and Date

Child's Name

Signature and Date

Investigator/Delegate's Name

Signature and Date

Witness' Name

Signature and Date

The investigator or a member of the research team will, as appropriate, explain to your child the research and his or her involvement. They will seek your child's ongoing cooperation throughout the study.

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.

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