The BedMed Study

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Research suggests it might be possible to improve health outcomes for people living with high blood pressure. With your help, we can find out.

Why is this study being conducted?

For those with high blood pressure, medications reduce the risk of heart attack and stroke. How effective these medications are may depend on the time of day they're taken. A European study suggests that taking blood pressure pills at bedtime, instead of in the morning, may reduce heart attacks and strokes by more than 50%. The BedMed Study is designed to determine if this is true.

Where will this study take place?

Wherever you are. Initial contact with the study team is by phone. Consent and follow up interviews can be done either by phone or online survey.

What is involved if I participate?

You may be asked to change the time you take your blood pressure medication. You'll be randomly assigned to take those medications (as tolerated) either in the morning or at bedtime for the duration of the study - up to 3 years. If you take medications at both times, you are still eligible to participate.

Which medications you use, and all other decisions regarding changes to these medications, will stay between you and your health care provider. If you need to change back to your original medication timing, you are able to do so. Whether you choose to participate or not will have no impact on your relationship with your healthcare team.

When will the study start?

The study begins after you speak with the study team by phone. Please don't change the time of day that you take your blood pressure medications before talking with your healthcare provider. Participation in this study is voluntary and you may withdraw at any time without having to give a reason.

Call the study team toll free at: **1-844-492-7570** (M-F, 7am – 5pm MST)

Email the study team at: **BedMed@ualberta.ca**
Visit the study website at: **pragmatictrials.ca/BedMed/**

The study will involve these steps:

1 Call: 1-844-492-7570

Our study staff will talk with you to see if the study is a good fit for you and answer any questions.

2 Consent

Consent can be done through mail or online survey. The study team will also collect medical history questions from you over the phone.

3 Randomization

A) You will be randomly placed into either the morning or evening group. You will record this on the "Medication Worksheet" at the back of this package, along with a list of your blood pressure medications.
B) You might see your health care provider if you need to change the time of one or more medications.

4 Follow-ups

The study team will call you one week later if there is the possibility of medication timing being changed. After this, follow-up interviews are at six weeks, six months, and every six months thereafter until the study is done. Interviews from month six onward are by phone or online survey if you prefer.

What are the Benefits?

One in five adult Albertans has high blood pressure. Whether or not we confirm benefit to bedtime prescribing, your participation will help answer an important question surrounding medications used by millions of people worldwide.

What are the Risks?

Morning Medication use

According to previous research, it's possible that there 's a higher risk of heart attack and stroke for those who take their blood pressure medications in the morning (compared to those who use them at bedtime). We don't know if this is true, which is why we're conducting this study.

Bedtime medication use

There are **no established risks** to using blood pressure pills at bedtime but we're closely watching for three possibilities:

1. Best evidence suggests it's not the case, but certain blood pressure pills might increase the number of overnight trips to the bathroom to urinate.
2. Having lower blood pressure overnight may lead to dizziness and potential for falls and fractures.
3. Lower blood pressures overnight might lead to reduced blood flow to the back of the eye in patients with glaucoma, and this may adversely affect vision. For this reason, those with glaucoma are excluded from participating.

Study Confidentiality

All information you provide is confidential. It will be kept in a locked cabinet in a locked research office or on an encrypted computer that's password protected, and only accessible to study investigators and staff. We will do everything we can to keep this data private. No study-related data that includes your name will ever be released outside of the study doctor's office. We will make every legal effort to make sure that your health information is kept private.

Throughout the study, we will be collecting your health data during our phone interviews with you.
We will also use your Personal Health Number (PHN) to link this study data to relevant records from your hospital, emergency room, physician office visits, and pharmacy data. The personal health information that we get from these records will be limited to what is needed for the study. If you leave the study, we will not collect new health information about you, but we will need to keep the data that we have already collected.

After you have completed the study, all of the identifying information (i.e., name and contact information) will be removed and your record will be labeled with a study ID that doesn't resemble your name. Your information will be stored in an encrypted, password protected electronic file. We will keep a separate list (in a locked cabinet) that links your name to the study ID number if it's ever necessary to relink you to your data. We will store this data for a minimum of 5 years after the end of the study. The results of this study will be used for publication, but will not identify any participants in any way. To maximize the value of this study after our analysis is complete, we will make our raw data available over the Internet (with all identifying information removed) so that other research groups can verify our findings and explore questions of their own.

For any concerns about your treatment or rights as a research subject in Alberta, contact the Research Ethics Office, University of Alberta at 780-492-2615 or e-mail them at reoffice@ualberta.ca). These offices have no direct involvement with this project.

Medication Worksheet

Your interviewer will help you fill out this table. Please keep this sheet for your records.

For the duration of the study, my blood pressure medication(s) have been assigned to:

A) Morning ***B) Bedtime***

My current medications:

Drug Name	Strength	Number of Tablets (example ½, 1, 2)			
		Morning	Noon	Dinner	Bedtime

Interview Dates: You will have telephone follow-up interviews with our study team at one week, six weeks, six months, and every six months after your initial medication review visit. At month six, you may choose to continue with telephone follow-ups or switch to email. If you choose email follow-ups, your interviewer will provide you with a five-digit code and explain the process.

Online survey access information
(Applicable for online follow-ups)

Five-digit code: _____

Interviewer name: _____

For questions regarding the study or how to use this form please contact us:

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