PlacEbo-controlled, Randomized, Patient-Selected Outcomes N-of-1 triALs (PERSONAL-pilot): Alpha-blockers for Lower Urinary Tract Symptoms

NCT05415748

February 09, 2023

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: PlacEbo-controlled, Randomized, patient-Selected Outcomes N-of-1 triALs (PERSONAL): alpha-blockers for lower urinary tract symptoms

Research Project Director:	Benjamin N. Breyer, MD, MAS; Associate Professor of Urology 1001 Potrero Ave, Suite 3A2, San Francisco, CA 94110 Email: Benjamin.Breyer@ucsf.edu, Phone: 628-206-8805 Scott R. Bauer, MD, ScM, Assistant Professor of Medicine & Urology Stacey A. Kenfield, ScD; Associate Professor of Urology and Epidemiology & Biostatistics
Study Coordinator:	Anthony Enriquez, Phone: (628) 206-8805 Anthony.Enriquez2@ucsf.edu

This is a research study about gathering urinary symptom and medication side effect data on a smartphone while stopping and restarting your prostate medicine. The study investigators, Scott Bauer, Stacey Kenfield, or Benjamin Breyer will explain this study to you.

STUDY SUMMARY

Introduction: We are asking you to consider taking part in a research study being done by study doctors Scott Bauer, Stacey Kenfield, and Benjamin Breyer at UCSF.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to make a decision about participating. You can discuss your decision with your family, friends, and health care team.

Purpose of the study: The primary purpose of this study is to determine whether or not tamsulosin is still helping your urinary symptoms or causing side effects. Secondly, we will provide you with a personalized report at the end of the study on how helpful or harmful tamsulosin is for you.

Study Procedures: If you choose to be in this study, you will be asked to monitor and record your urinary symptoms and medication side effects every day for 12 weeks using online surveys accessible from your smartphone. During this period, you will alternate taking your usual prescription of tamsulosin medication or a placebo pill provided by the research team. After the 12-week period, you will be asked to take an end of study questionnaire and to participate in a 15-30-minute interview. This interview will be recorded and transcribed.

Optional: After the 12-week study period, you will be asked to participate in a continuation study. For an additional 3 weeks, you will continue to answer daily symptom and side effect questions and provide 3 blood draws. The purpose of the blood draws is to determine how the level of tamsulosin in your blood changes after stopping it temporarily and how these changes relate to your urinary symptoms and side effects.

You will be in this study for a minimum of 12 weeks. Participation in the main study requires a total time commitment of approximately 5 hours and 30 minutes over a 12-week period. We also have a continuation part of the study that is optional and will be discussed later in the consent form.

Possible Risks: There are risks to taking part in a research study. Some of the most likely risks of participation in this study include:

- You may experience mild worsening of your urinary symptoms after stopping tamsulosin temporarily.
- You may experience discomfort when completing the daily activities or answering survey questions.
- There is the potential for loss of personal data. While we will make every effort to ensure that your data remains confidential, it may be lost due to loss of your device, hardware or software failure, and other reasons. Your data is extremely important to us and the steps we take to protect it are described in the Confidentiality section below. If you feel uncomfortable with any study activity, you may discontinue participation at any time, either temporarily or permanently.
- Other risks will be discussed later in the consent form.

Possible Benefits: You will receive a personalized report on how helpful or harmful tamsulosin is for you after participating in this study. The information that you provide may also help health professionals learn more about how to improve measurement of urinary symptoms and medication side effects for other men with benign prostatic hyperplasia.

Your Other Options: You do not have to participate in this study.

Please talk to your doctor about your choices before agreeing to participate in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you have a diagnosis of benign prostatic hyperplasia (BPH) and are taking a medication called tamsulosin for urinary symptoms caused by BPH.

Why is this study being done?

The primary purpose of this study is to determine whether or not tamsulosin is still helping your urinary symptoms or causing side effects. Secondly, we will provide you with a personalized report on how helpful or harmful tamsulosin is for you.

This study is sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases.

How many people will take part in this study?

About 20-40 people will take part in this study.

What will happen if I take part in this research study?

If you choose to be in this study, you will be asked to monitor and record your urinary symptom and medication side effect data daily for 12 weeks using online surveys accessible from your smartphone. During this period, you will be taking your usual prescription of tamsulosin medication or a placebo pill provided by the research team. After the 12-week period, you will be asked to take an end of study questionnaire and to participate in a 15-30-minute interview that will be recorded and transcribed.

Optional: After the 12-week study period, you will be asked to participate in a continuation for our study. For an additional 3 weeks, you will continue to answer daily symptom and side effect questions and provide 3 blood draws.

Before you begin the main part of the study...

- You will answer screening questions over the phone with our research team to find out if you can be in the study.
- You will have an orientation phone call with members of our research team to learn about our study procedures and directions on how to monitor your symptoms through our online surveys.

- You will be "randomized" during the study period to continue taking your tamsulosin or to replace it with a placebo pill. *Randomization* means that you are put into a group by chance. A computer program will place you in one of the groups. Neither you nor your

doctor can choose the group you will be in. You will have an equal chance of being placed in any group. A *placebo* is an inactive substance and the *placebo* pill will look identical to the tamsulosin pill.

- At different times during the 12 weeks, you will be assigned to take your usual tamsulosin medication or a placebo pill for 2-week periods. Every participant will take tamsulosin for two 2-week periods and take the placebo for two 2-week periods, with 1-week washout periods between them, totaling 12 weeks. The order of these periods is randomly assigned for each person.
- Your daily tracking of symptoms and side effects will help us determine whether tamsulosin is helping with your urinary symptoms or causing side effects.

During the main part of the study...

- The main part of the study will be a 12-week monitoring period.
- During this period, you will be taking your usual tamsulosin medication or a placebo pill.
- Using our online survey accessible from your smartphone, you will record your urinary symptom and medication side effect data every day.

When you are finished with the main study monitoring of 12 weeks…

- You will be asked to take an end-of study-questionnaire
- You will be asked to participate in a 15-30 minute end-of-study-interview via Zoom Conferencing.
    - You will be provided with a unique ID, teleconference phone number, and access code for the call. Your phone number you call from will not be recorded or used in any way. One of our study doctors will conduct this interview, however, your name and medical record number will not be given. The audio recording will be kept until the research study is completed.
- After the 12-week study period and end-of-study interview/questionnaire, you will be asked to participate in a continuation study. This is an optional part of our research. Details are as followed:

***Continuation Study (Optional)*:**
If you agree to participate in our continuation study…

- This part of the study will consist of an additional 3-week study period.
- You will continue to answer daily urinary symptom and side effect questions for 3 more weeks.
- Blood drawing (venipuncture) will be used to determine the level of tamsulosin in your blood.

- We will study how the level of tamsulosin in your blood changes after stopping it temporarily and how these changes affect your urinary symptoms and medication side effects.
  - A blood sample will be drawn at baseline by inserting a needle into a vein in your arm. Each sample will be approximately 0.2 teaspoons; a total of about 0.6 teaspoons will be drawn for the whole study.
  - After providing a baseline blood sample, you will complete daily survey assessments and take your normal tamsulosin medication for 5 days. Then, you will be asked to stop your tamsulosin for the remaining 10 days of the continuation study in order to measure how quickly tamsulosin is cleared from your blood and how these changes affect your urinary symptoms and medication side effects.
  - You will be scheduled for a second blood draw on your second day off tamsulosin. You will have your third blood draw 24 hours later (e.g. 9 am on Tuesday and 9 am on Wednesday) and remain off the medication for 10 days total.

Study location: Most study procedures will be done remotely over the phone or using Zoom Conferencing. Study procedures that require an in-person visit such as the blood draw, will take place at UCSF Medical Center at Mission Bay or Parnassus.

How long will I be in the study?

For the main part of the study, you will be asked to alternate taking your usual tamsulosin medication and placebo for 12 weeks. After you are finished with this 12-week monitoring period, the study doctor will ask you to complete an end-of-study questionnaire and interview. Participation in this main study requires a total time commitment of approximately 5 hours and 30 minutes over a 12-week period.

If you agree to participate in our continuation part of the study, you will be asked to continue daily urinary symptom and side effect assessments for an extra 3 weeks and provide 3 blood draws. Participation in this continuation study, in addition to the main study, requires a total time commitment of approximately 2 hours and 30 minutes.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from medication tampering can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. You should talk to your study doctor about any side effects you experience while taking part in the study. Risks and side effects related to this study include those which are:

Non-Physical Risks:

- You may experience discomfort when completing the daily activities or answering survey questions.
- There is the potential for loss of personal data. While we will make every effort to ensure that your data remains confidential, it may be lost due to loss of your device, hardware or software failure, and other reasons. Your data is extremely important to us and the steps we take to protect it are described in the Confidentiality section below. If you feel uncomfortable with any study activity, you may discontinue participation at any time, either temporarily or permanently.

Physical Risks:

- You may experience mild worsening of your urinary symptoms after stopping tamsulosin temporarily.
- Randomization risks: You will be assigned to a treatment program by chance, and the treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.
- Placebo risks: When you are randomized to receive placebo, your urinary condition will go without tamsulosin treatment for 2 weeks.
- Blood drawing (venipuncture) risks (*Continuation Study Only*): Drawing blood may cause temporary discomfort from the needle stick, bruising, infection, and fainting.

Are there benefits to taking part in the study?

There are no direct benefits to study subjects. Participants in this research study may find that the study interventions are effective in providing information that may aid in lower urinary tract symptoms self-management and in medication adherence.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Please talk to your doctor about your choices before deciding if you will take part in this study.

How will my specimens and information be used?

Researchers will use your specimens and information to conduct this study. Specimens and information gathered during this research study will only be used for this study. They will not be shared with other researchers.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records and may be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the University of California
- Representatives of the National Institutes of Health **Are there**

any costs to me for taking part in this study?

No.

Will I be paid for taking part in this study?

In return for your time and effort, you will be given gift cards totaling an amount of up to $100 in value for completion of the study. You will be paid monthly over a period of 3 months.
Payment schedule:

- $20 after 1st month
- $30 after 2nd month
- $50 for study completion

Optional:
If you agree to participate in our continuation study, you will be given additional gift cards totaling an amount of up to $100 in value. Payment schedule:

- $50 after 1st blood draw
- $50 after 2nd blood draw

What happens if I am injured because I took part in this study?

It is important that you tell your study doctors, Benjamin Breyer, Scott Bauer or Stacey Kenfield, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at 628-206-8805.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor Benjamin Breyer, MD at 628-206-8805.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814.

OPTIONAL RESEARCH (*Continuation Study*)

Please note: This section of the informed consent form is about optional research studies that are being done with people who are taking part in the main study. You may take part in these optional studies if you want to. You can still be a part of the main study even if you say "no" to taking part in any of these optional studies.

You can say "yes" or "no" to each of the following studies. Please mark your choice for each study.

- This part of the study will take part after the main 12-week monitoring period.
- You will continue to answer daily urinary symptom and side effect questions for an additional 3 weeks.
- Blood drawing (venipuncture) will be used to determine the level of tamsulosin in your blood.

- We will study how the level of tamsulosin in your blood changes after stopping it temporarily and how these changes affect your urinary symptoms and medication side effects.
  - A blood sample will be drawn by inserting a needle into a vein in your arm. Each sample will be approximately 0.2 teaspoons; a total of about 0.6 teaspoons will be drawn for the whole study.
  - After providing a baseline blood sample, you will complete daily survey assessments and take your normal tamsulosin medication for 5 days. Then, you will be asked to stop your tamsulosin for the remaining 10 days of the continuation study in order to measure how quickly tamsulosin is cleared from your blood and how these changes affect your urinary symptoms and medication side effects.
  - You will be scheduled for a second blood draw on your second day off tamsulosin. You will have your third blood draw 24 hours later (e.g. 9 am on Tuesday and 9 am on Wednesday) and remain off the medication for 10 days total.

Just like in the main study, we will do our best to make sure that your personal information will be kept private.

Please put your initials in the "YES" or "NO" box to indicate your answer.

I choose to take part in the continuation part of this study.

YES	*NO*

Someone may contact me in the future to ask me to take part in more research.

YES	*NO*

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____ _____

Date Participant's Signature for Consent

_____ _____

Date Person Obtaining Consent