

Procedures/Risks: blood draws, IV lines, vitals_template

Blinding/Masking

You will be ‘masked’ (or ‘blinded’) to the study medication [treatment, intervention or group assignment] that you will receive during the course of this study. This means that [neither] you, [the study doctor, nor the research staff you see at your study visits] will not know to which group you have been assigned. This information will be kept by the study coordinator and made known [revealed to you] only in the event of an emergency.

Fingerstick:

Procedure: Your finger will be pricked by a small needle in order to obtain a couple drops of blood [to measure (fasting) blood glucose and/or blood lipid levels]

Risk: From the fingerstick you may feel slight pain- a feeling similar to that of being pricked by a pin.

Fasting:

Procedure: You will be asked to not eat or drink anything for 10 to 12 hours before [each of] your study visit[s]....

If you are eligible and wish to continue with the study, you will be scheduled for X visits [to the Clinical Research Center (CRC), a hospital research unit]. You will be asked to avoid eating any foods or drinking any liquids after midnight, before [each of your CRC visit(s)]. [You will be given breakfast after each visit’s blood draw on the CRC]. Information about each visit is outlined in the table in this document.

Risk: It is possible/There is a small risk that your blood sugar may become low from fasting. You might feel lightheaded, dizzy or faint. Should you begin to experience any of these effects, please notify one of the research staff.

Heplock:

Procedure: [An alternative method to administer the study drug is to use] A heplock is a small thin tube for drawing blood samples. The heplock would be placed into a vein in your arm and left in place. The heplock may stay in your arm for X days. Before going home, you will be given instructions on how to protect the heplock by using cling wrap, and with tape before you shower. You will be given syringes without needles to take home so you can push solution through (“flush”) the heplock twice when you are at home. You will need to ‘flush’ the heplock

once before going to bed, and then again when you wake up in the morning. If the heplock is in the arm that you use the most, you may need assistance at home with the ‘flushes’. If you live alone, you may need to plan to stay with a family member or friend for a couple of nights or they with you while you have the heplock in your arm. This will help you push the solution through as well as ‘flush’ the heplock.

Risk: Risks associated with blood drawing or the placement of a heplock may include pain, bruising, infection, lightheadedness, fainting, blood clots, and bleeding or other discomforts at the [blood drawing] site. Occasionally, there is swelling around the area where the needle or heplock enters the body. There is also a small risk of infection.

Infusions:

Procedure: A needle with a plastic tube attached will be inserted into a vein in your arm. This is known as an intravenous line or “IV”. Through this IV study medication will be administered [over a period of time].

Risk: You may experience a “burning-like” sensation at the site of the infusion, or through the vein. Certain medications may be added to the solution to reduce this discomfort.

Heparin, also included in the infusion solution, is a commonly used blood thinner that is used to prevent clotting of the vein used for the intravenous infusion. A primary side effect of heparin is an allergic reaction that could lead to bleeding or blood clots.

Procaine, also included in the infusion solution, is a local anesthetic that is added to prevent stinging or discomfort during the intravenous infusions. The main side effect is the possibility of an allergic reaction.

Sodium bicarbonate is a naturally occurring substance that increases the ability of the kidney to excrete impurities. It is included in the infusion solution.

If your heart is weak, you may be at risk of developing fluid in your lungs, swelling in your ankles, or rapid weight gain. This fluid accumulation is also known as heart failure, and is a result of the heart’s inability to tolerate the amount of fluid that will be infused. Your weight will be monitored to make sure that you are not accumulating fluid. If your doctor determines that your weight gain is related to the infusions, the infusions will be temporarily stopped. Additionally, your doctor may determine it is necessary to give you a diuretic (water pill) in order to prevent any further fluid from accumulating in your lungs which may lead to shortness of breath. People who already have a history of decreased heart function will be at greater risk. If you have had fluid in your lungs due to a weak heart within the last XX weeks/months, you will not be permitted to participate in the study.

Intravenous catheter:

Procedure: A needle with a plastic tube attached will be inserted into a vein in your arm. This is known as an intravenous line or “IV”. Through this IV [study] medication will be administered over a period of time.

Risk: Risks associated with having an IV placed or blood drawn, may include mild discomfort, bruising, bleeding, blood clot and a very slight risk of infection at the needle puncture site. Some people who have needle punctures may become lightheaded, nauseous or faint. Having an IV placed and/or blood drawn, may cause discomfort or minor bleeding and the possibility of bruising at the site of the IV or blood draw. There is also a slight risk of infection at the site of the needle puncture. Although rare, some people have experienced nausea, light headedness, and fainting in association with an IV placement.

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Peripherally inserted central catheter (PICC)

Procedure: A peripherally inserted central catheter (PICC) is a catheter placed in the vein that should remain in place for the duration of your participation in the study [as long as the catheter continues to function and remains free of infection]. This catheter will only be used if the nurses are unable to put a needle in your vein(s) each time the [study] medication is given. A family member and/or someone else that you choose, will be instructed how to care for the PICC line. Daily ‘flushes’ of sterile salt water (sterile saline) are necessary to keep the PICC line open, and you and/or a caregiver will be instructed on how to do this.

Risks: The risks of placing a PICC are pain, redness, bleeding, infection, and exposure to x-rays. In addition, the PICC line may break, or be unusable because of a blood clot in the catheter line. There is about a 1 in 5 chance of any of these complications occurring. If they do, it may be necessary to place the PICC line in your other arm. If this is not possible it may be necessary for you to stop the study. The PICC is placed in the Radiology Department using an x-ray machine for placement. The x-ray would deliver approximately 75 millirems of radiation. “Scientists estimate that the average person in the United States receives a dose of about 360 millirems of radiation per year. Eighty percent of that exposure comes from natural sources: gas in the atmosphere, the human body, outer space, and rocks and soil. The remaining 20 percent comes from man-made sources, primarily medical x-rays.” (quote taken from <http://www.epa.gov/fadiation/rpage/rpage2.html>). No dye (contrast agent) is used during or after the placement of the PICC.

Saliva sampling

Procedure: In order to obtain the sample of saliva a 1-inch cotton ball will be placed in your mouth. You will have to keep this in your mouth for at least 8 minutes.

Risk: In the process of obtaining the saliva sample, you may also experience some mild discomfort from holding the cotton roll between your cheek and gum. You might also experience dry mouth and mild skin irritation (redness and itching).

Screen Visit

Procedure: The first visit for this study is called a “screening visit.” At this visit your eligibility for this study will be determined. The following procedures will be conducted during the Screening Visit:

- Your medical and disease history will be taken. The study doctor will also review the medications that you are currently taking (and have taken in the past).
- You will be given a physical examination, and your height and weight will be taken.
- Your vital signs (blood pressure, heart rate, breathing rate, temperature) will be taken.
- A 12-lead electrocardiogram (ECG) will be performed to measure electrical activity of your heart.
- A chest x-ray may be done if you have not had one within the past 3 months.
- A blood sample will be drawn for routine and special blood tests (blood cells count and checking levels of different substances in the blood).
- Hepatitis B or C screening. State law requires that the results of positive tests for hepatitis be reported to a local health agency.
- A urine pregnancy will be done if you are a female capable of bearing a child.
- Urine tests will be done.

Urine collection

Procedure: You will have a 24 hour urine collection to test kidney function every week. The 24 hour urine test requires that you save all of your urine during a whole day (24 hours) in a special container that will be provided to you.

Procedure: You will also need to collect all of the urine you produce from the time you leave the study doctor’s office until you return the next morning. You will be given a special container [with a wide opening and a leak proof screw cap] in which to store the urine. It does not matter how much urine you collect, just as long as you collect all of the urine that you pass between leaving the study doctor’s office and your return the next morning. If you need to have a bowel movement, you should try to collect the urine separately. Any urine passed during a bowel movement should be collected. If you need to pass your urine in the middle of the night, you are to collect that as well. Your study doctor will give you instructions on how to store the urine container. Please note the exact time of the final urination before you return to the study doctor’s office.

Venipuncture:

Procedure: You will have about XXmilliliters (approximately X tea/table-spoons) of blood drawn by a needle from a vein in your arm.

There are chemicals in your body that will be measured in the blood that will be drawn from the vein in your arm. Approximately XX tablespoons of blood will be taken at each visit [fasting: and you will not be able to eat or drink anything for at least 10/12 hours before your blood is drawn].

Risk: Having blood drawn may produce discomfort or minor bleeding and the possibility of bruising at the site of the needle puncture. There is also a slight risk of infection at the site of the needle puncture. Although rare, some people have experienced nausea, light headedness, and fainting in association with a blood draw. Trained medical personnel will perform the blood collection procedures for laboratory tests and will make every effort to minimize any discomfort.

The site from where your blood is drawn could become infected or bruised. A blood draw may be painful and can make you faint. The possible risks associated with blood drawing are pain, bleeding, fainting, bruising, infection and/or hematoma (blood clot under the skin) at the injection site. If you develop bruising, this will go away after a couple of days and can be treated with warm compresses and/or medication. Using well-trained and experienced nurses will lessen these risks.

You may experience side effects of having your blood drawn. These side effects can include pain, swelling, bruising, tissue discoloration or scarring around the vein that is used to draw the blood sample. There is a possibility that some of these tissue changes and scarring could become permanent. There may be the risk of infection or clotting from having your blood drawn. There is also the possibility that you may faint during or shortly after the needle is inserted. If you feel dizzy, then please tell someone and then sit or lie down to avoid falling and hurting yourself.

The blood samples taken for this study will be used for research purposes *only*. The results will not replace your usual medical care (for example, your cholesterol level will not be reported to you or your doctor). If at anytime you decide you do not want your blood used in the study, you can contact [PI or study coordinator and telephone contact information].

Vital signs:

Vital signs will be taken on you [at each visit]. Vital signs include measurements of your pulse (heart rate), respirations (breaths per minute), blood pressure, height, weight and body temperature.