

Study Welcome Booklet

Thank you for exploring
another path

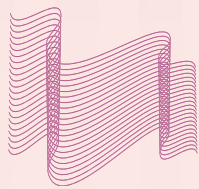


What to expect during
the endometriosis
research study



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STUDY





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Welcome to the Schumann Study

Thank you for taking part in this very important research study. Not only will you have an opportunity to learn more about your condition, but you may also help advance medical knowledge of endometriosis.

Our study staff is here to support you throughout the study. This guide will tell you more about what to expect while you are participating.

Our office is conducting the study to see if the investigational oral medication, P2X3 antagonist, may safely and effectively reduce endometriosis pain. The study is also trying to determine the optimal dose of the study medication.

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Study Overview

There are three phases of participation in the study:

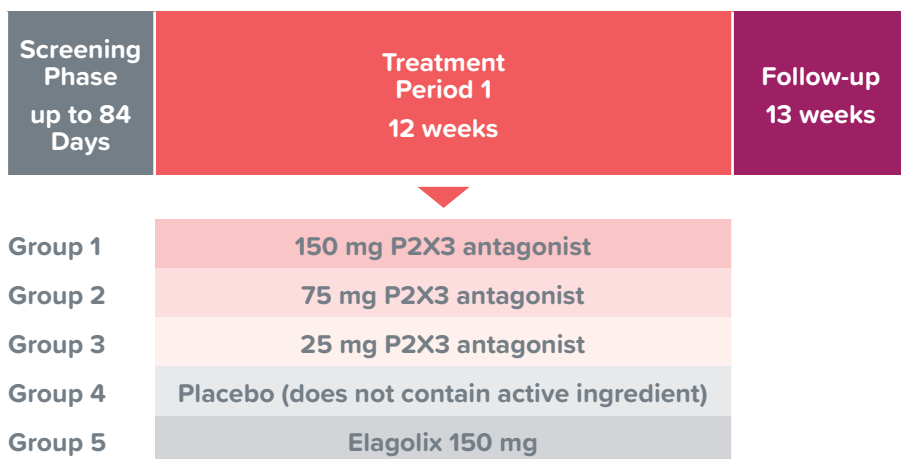


In the treatment and follow-up phases, the study team will perform a variety of tests and procedures to see if P2X3 antagonist is safe and effective. Your health will be closely monitored by the study team throughout the study.

Treatment Groups

You will have a 4 in 5 chance of receiving active treatment (either P2X3 antagonist or Elagolix) and a 1 in 5 chance of receiving placebo. In order to prevent bias, neither you nor the study team will know which group you have been assigned to.

You will be assigned to 1 of 5 treatment groups:



Treatment

The treatment period

You'll take the study medication every day for 12 weeks.

You will come to the study office for study visits at regular intervals.

At every visit, you will answer questions about your symptoms, your health, and your medications. Between visits, you will use the eDiary daily to record your symptoms, your pregnancy tests, and your study related medications.

Some study visits may include tests and procedures, such as:

- Physical exams
- Gynecological exams
- Pregnancy tests
- Blood and urine tests
- Ultrasounds
- Questionnaires

Follow-up

After receiving the final dose of the study medication, you will come back to the study office for one or two follow-up visits either 5 or 13 weeks later. Some of the same tests and procedures that you have undergone during the study will be repeated. The follow-up visit is to check on your well-being and health.

Reminders About Medications

During the treatment periods, you should take your study medication twice a day orally. If you miss a dose of the study drug, you should take the tablet as soon as possible. If you miss a dose by more than 6 hours, you should not take the missed dose but simply resume the usual dosing schedule.

Furthermore, you should NOT take your study drug at home on the days of Visit 2, 3 & 5. During these visits, you will take the study medication at the study office.

There are certain types of medication you will not be able to take during the study. After you sign the Patient Information and Consent Form, your study doctor may have you stop certain medications.

Unless it is an emergency, it is important not to start any new medications without first telling your study doctor.

Tell the study doctor right away about any changes to your medications, including:

- New prescription medications
- Changes to medications—that is, if you stop taking a medication or begin taking a different dose
- New over-the-counter medications or supplements

You must use **nonhormonal contraception** until the end of the study to ensure that you do not get pregnant. If your partner has had a vasectomy or you have had your tubes tied, no other form of contraception is needed. Using a hormonal contraceptive (such as birth control pills) is not permitted, as it could interfere with the study results.

Rescue Medications for Endometriosis Pain

You are allowed to take medication for your endometriosis pain during the study in addition to your study medication if needed. However, you must follow these specific directions for taking pain medication.

1. Only take pain medication that is prescribed to you by the study doctor. This may include:
 - Over-the-counter pain medication, such as ibuprofen.
 - Prescription narcotic pain medication (such as tramadol). The study doctor can give you a prescription for this medication if you need it.
2. Pain medication should be taken **only when you experience endometriosis pain. You should not take pain medication to prevent endometriosis pain.**

Using pain medications other than what is prescribed to you could affect the study results. The table below describes the type of pain medications allowed.

Medication Name	Strength
Ibuprofen	400 mg
Acetaminophen/Paracetamol	500 mg
Tramadol	50 mg

*The narcotic pain medication will be prescribed in addition to or substituting for ibuprofen. All pain medications should be used according to the product's prescribing information.

Your daily use of supportive pain medications for endometriosis related pain should be recorded in your eDiary. Include the dose and the number of pills taken within a 24-hour period.

Study Tests and Procedures









Tests and procedures you will take/undergo during the study include the following:


































- **Ultrasound:** The most appropriate ultrasound method (transvaginal) will be used throughout the study to help the study doctor better see your endometriosis lesions.
- **Pregnancy tests:** A urine pregnancy test will be taken at some study visits. In addition, you will be given home pregnancy tests. A test must be done if you are concerned about being pregnant. **If the result of a home pregnancy test is positive, you should stop taking the study drug and contact the study staff immediately.** If you get pregnant during the study, your study participation will end.
- **Electronic diary (eDiary):** You have been given an eDiary; please use this device daily to record the following:
 - » When you take your study medication
 - » If you take an at-home pregnancy test—and what the results are
 - » Your symptoms
 - » Use of supportive pain medication for endometriosis related pain
 - » Other important study related information

It is very important that you remember to use the eDiary every day, preferably at the same time. You should bring the device to each study visit to review with the study team. You will return the device to the site at the end of the study.

Schedule of Events

These assessments will be done during the visits below:

-  Physical exam
-  Gynecological exam
-  Transvaginal ultrasound
-  Blood draw
-  PK blood draw
-  Questionnaires completed at site
-  Randomization phone call
-  Actigraphy (Only participants who consented.)

Visit	Assessments
1a	     
1b	
2*	    
3*	  
4	   
5*	    
6	    
7	    

*Note: Take morning dose of investigational oral medication at the study site.



If you have any questions or concerns, please call your study doctor or another member of the study team.

Your study doctor

Name:

Phone:

Your study coordinator

Name:

Phone:

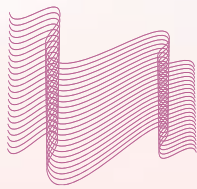
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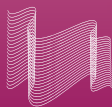
Phone:

Study location

Address:



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