



INANNA STUDY
(Protocol Number: MT-2990-A01)

**A Phase 2, Randomized, Double-blind, Placebo-controlled
Study to Assess the Safety and Efficacy of MT-2990 in Women
with Endometriosis Experiencing Endometrial Related Pain**

**Important information to know about your decision to participate.
This tool does not replace the informed consent form and process.**

What is a clinical research study?

- A clinical research study is designed to test the safety and effectiveness of an investigational medication in a group of volunteers
- Regulatory agencies use information from clinical research studies to decide if a medication is safe and effective for patients
- Every clinical research study (including this one) is monitored by an Institutional Review Board (IRB). An IRB is a group of healthcare professionals and community members who help make sure that research is done ethically and that the rights of patients are protected
- Participation is completely voluntary. You may leave the study at any time, for any reason
- There is no penalty or loss of benefits if you decide not to participate in the study or to leave the study after you've joined



What is the purpose of this study?

- This study is testing whether an investigational medication called MT-2990 could reduce pain associated with endometriosis
- MT-2990 is different from other medications that are commonly used to treat endometriosis. It is designed to specifically target cells in the body's immune system that cause inflammation associated with endometriosis pain. This study will help measure how effective and safe it might be in reducing that pain
- About 76 women (aged 18-49 years old) with endometriosis will participate in the study
- The study is being conducted at about 38 research sites in the United States

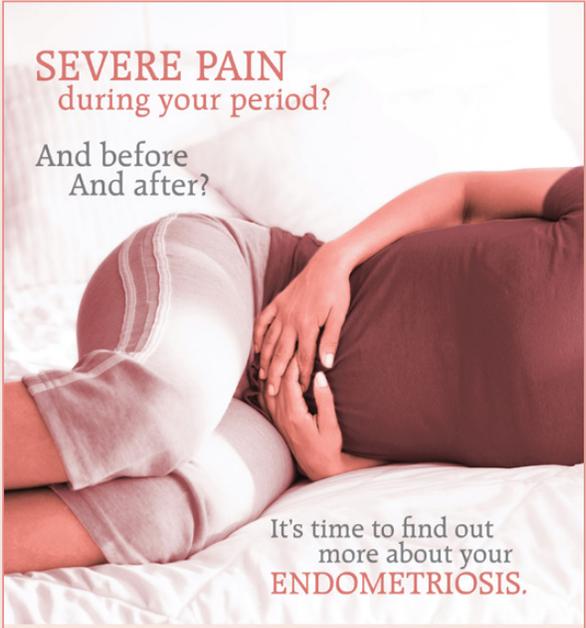


Who may qualify for this clinical research study?

Women who meet the following basic criteria may be able to participate:

- Are between 18 and 49 years of age
- Have been diagnosed with endometriosis within the last 5 years
- Have a 21-38 day menstrual cycle
- Are not pregnant, nursing or planning a pregnancy within the next 12 months
- Are willing to stop taking current hormonal endometriosis therapies (use of nonhormonal contraception methods is required during the study)

Other criteria will be reviewed by the study staff to determine eligibility.



SEVERE PAIN
during your period?
And before
And after?

It's time to find out
more about your
ENDOMETRIOSIS.

HELP US STUDY AN INVESTIGATIONAL MEDICATION THAT MAY REDUCE ENDOMETRIOSIS PAIN.

The INANNA study is evaluating an investigational medication in women with moderate or severe endometriosis pain. You may qualify to participate if you:

- Are between 18 and 49 years of age
- Have been diagnosed with endometriosis within the last 5 years
- Have a 21-38 day menstrual cycle
- Are not pregnant, nursing or planning a pregnancy within the next 12 months
- Are willing to stop taking current hormonal endometriosis therapies (use of nonhormonal contraception methods is required during the study)

Other criteria will be reviewed to determine if you qualify for this study. Participation in the study will last about 1 year and will require about 9 visits to the research clinic and 2 scheduled follow-up phone calls. The study medication, clinic visits, laboratory tests, and procedures that are part of the study will be provided at no cost. You may also be compensated for your time and study-related travel expenses.

For more information, please contact:



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What are some possible side effects of MT-2990?

The side effects reported in a previous study of 40 volunteers were:

- Diarrhea
- Abdominal pain/discomfort
- Discolored feces
- Pain in the gums or teeth
- Blisters in the mouth

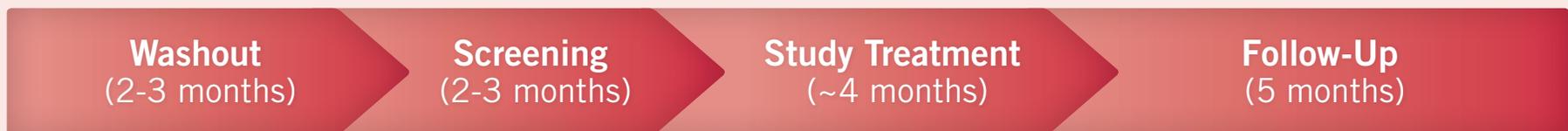
There may be other unknown side effects. Please see the Informed Consent Form for a more complete list of possible side effects.



How long does the study last?

The study lasts up to a year and is divided into 4 phases:

- **Washout Period** (around 2-3 months): Women who are using hormonal therapies will need to stop using these and will need to start using study-approved methods of birth control. You may also need to stop using certain pain-relieving medications and switch to study-approved options.
- **Screening Period** (around 2-3 months): Tests and assessments will be performed to determine whether you meet the criteria to participate in the study. In addition, you will need to have two menstrual cycles that are 21-38 days long during the Screening Period to be eligible to participate in the study.
- **Study Treatment Period** (around 4 months): You will be randomly assigned (like the flip of a coin) to study treatment with either the investigational drug or placebo (an inactive substance). You will receive the study treatment through IV infusion once each month and attend 4 other visits for tests and to check on your health.
- **Follow-Up Period** (around 5 months): You will receive 2 planned phone calls over this time to check up on your overall health, endometriosis-related pain, use of medications and whether you have had any hospital admissions or endometriosis-related surgeries.



How many study visits are there?

- Participation in the study will last about 1 year and will require approximately 9 visits to the research clinic and 2 scheduled follow-up phone calls



What happens at study visits?

- Medical history
- Physical examination including a pelvic exam
- Height, weight, vital signs
- 12-lead Electrocardiogram (ECG) to check heart function
- Blood and urine tests, including drug screening
- Pregnancy tests for all women who can become pregnant
- Questionnaires and other assessments about your health, endometriosis-related pain, and other symptoms
- Transvaginal ultrasound



The Informed Consent Form gives more details about which procedures occur at each study visit.

What are some potential risks and benefits?

- Your health may or may not improve
- The study medication may involve risks that are not known at this time, including possible life-threatening reactions



- Your health will be monitored and will be watched for side effects during the study
- Any new information about MT-2990 that is discovered during the trial will be explained to help you decide if you want to stay in the trial
- Please see the Informed Consent Form for a more complete list of possible risks

Will this study cost me anything?

- All study-related office visits, study-related medical procedures, laboratory tests, and study medication are provided at no cost to qualified participants
- Travel reimbursement may be provided. Ask the study staff if this is available



What is expected of study participants?

- Follow all instructions from the study doctor and study staff
- Complete the study-provided electronic diary (e-diary) every day
- Do not take any other medications (including over-the-counter products), vaccines, nutritional supplements, or herbal remedies without prior approval from the study doctor
- Do not change the dose of any doctor-approved medications or remedies you are taking without approval from the study doctor
- Tell the study doctor and staff if you have any concerns or changes to your health
- During the study, limit yourself to no more than 1 drink of alcohol per day (1 glass of wine, 1 12-ounce beer, or 1 mixed drink)
- Do not participate in other medical research studies while in this one
- If you are sexually active with a man who is not sterile, you must use 2 forms of study-approved birth control from the beginning of the study through 3 months after the last dose of study drug. Ask the study doctor about what forms of birth control may be used.



Summary

- You are being asked to consider participation in the INANNA study, which is evaluating an investigational medication in women with moderate or severe pain associated with endometriosis
- The study medication (MT-2990) and all study-related procedures will be provided to you at no cost
- There are important risks and benefits to consider
- Please review the Informed Consent Form carefully and make sure you understand it. You can keep a copy of the consent form
- If you decide to take part, you can end participation in the study at any time and for any reason

Thank you

Once again, we'd like to thank you for taking time to learn more about this study.

Research on endometriosis can only happen because women like you are willing to volunteer to participate in clinical studies. You may or may not benefit from the study, but other women might in the future.

We know you have much to consider. Please take your time and ask questions about anything you need clarified.

