MARS-17

Information about participation in the

MARS-17 Clinical Trial

Contact Information

Study doctor:

_____

Study coordinator:

_____

Other study team member(s):

_____

_____

_____

Telephone/email:

_____

_____

_____

Emergency telephone:

_____

_____

_____

Welcome to MARS-17,

a clinical trial for adults living with osteoarthritis (OA) knee pain

The MARS-17 clinical trial is testing an investigational drug called GSK3858279 (the "study drug") in people with OA knee pain. As a participant, you will play a key role in this clinical trial.

Taking part in this trial is completely voluntary. It is your choice. You are free to leave the trial at any time, for any reason. Your choice will not affect the medical care you may receive outside the trial.

This guide is provided for you to use throughout the trial. It includes information that we hope you will find helpful as well as space for you to take notes. If you have any questions, you should always feel free to ask the study doctor and team. You will have their full support in this trial.

What's Inside

Thank you for participating in the MARS-17 clinical trial. We appreciate your commitment to OA research. Please let the study doctor and team know how they can help make your trial experience better.

Being in a clinical trial

All rules and ethics that apply to standard medical care also apply to clinical trials. Being in a trial is much like going to see your doctor, though there are some key differences. For example, in this trial you will:

- Receive either an investigational drug or a placebo
- Have frequent medical appointments
- Undergo some tests and assessments that are not part of your usual medical care

The study doctor will follow a written plan called a protocol. This plan ensures that the trial will be done in accordance with standards and regulations. The plan has been reviewed by Institutional Review Boards and Ethics Committees. Their role is to protect your rights and welfare.

Clinical trials for OA knee pain

Current treatments for OA can help relieve pain. However, some treatments can have significant side effects or may not help people manage their pain effectively. The MARS-17 clinical trial is part of the effort to develop alternative treatments.

About the study drug (GSK3858279)

The study drug GSK3858279 is a type of medicine called a monoclonal antibody. Previous research has shown that GSK3858279 blocks the activity of a protein called CCL17 and may reduce pain. It is hoped that blocking CCL17 may reduce knee pain in patients with OA.

GSK3858279 has been previously studied in approximately 100 people in clinical trials. However, GSK3858279 is not an approved treatment. What we learn in this trial may help people with OA knee pain in the future.

What will happen during the trial?

You will be in this trial for up to 37 weeks as briefly described here.

Screening/Run-in (up to 6 weeks)

A screening process has shown that you are eligible to participate in this trial. This included a review of:

- Your medical history,
- Blood test results,
- X-rays, and
- Other assessments of your health

You will be asked to stop taking your current pain medications until you complete the study treatment period (in other words, from during the screening period up to the Week 16 visit). Your study doctor will advise you on when and how to stop taking your current pain medications. You will be able to take paracetamol/acetaminophen at doses of up to 3 grams/day and for a maximum of 4 days in a week any time during the trial except within 24 hours before and during study visits.

Study Treatment (16 weeks)

A computer will assign you at random (by chance) to a study group. Some groups will receive the study drug (2 in 3 chance); others will receive placebo (1 in 3 chance). The placebo has no active ingredients, which means it should have no true physical effect. Effects seen in participants who receive the study drug will be compared to what is seen in participants who do not receive it. You will not know what study group you are in. The study doctor also will not know.

You will receive injections of the study drug or placebo under the skin (subcutaneously). The study doctor will explain the study treatment schedule to you. Weekly study visits will include assessments of your health. You will have additional visits for the collection of blood samples after some study injections.

Follow-up (15 weeks)

After you complete the study treatment period, the study doctor will assess your health for 15 more weeks. You will have three additional visits. If allowed at your location, you may have the option for the first two follow-up visits to be done at your home. The study doctor will tell you if this is an option for you.

What will happen at study visits?

The study doctor and team will assess your health at study visits. Most visits will include:

- Injections of the study drug or placebo (during the study treatment period only)
- Review of your electronic diary (eDiary) compliance
- Brief physical exam
- Vital signs check (body temperature, pulse rate, respiratory rate, and blood pressure)
- Collection of blood and urine samples
- Pregnancy test (if applicable)
- Review of changes in your health and side effects
- Review of medication you may take during the trial

At some visits you will also have additional assessments, including:

- Questionnaires about your health and well-being
- Electrocardiogram (ECG) to check your heart activity
- Knee X-rays

The pages that follow include a schedule that shows the timing of visits and what will happen at them.

Study visit tips

Plan ahead. Let the study team know about any days you may be traveling, on vacation, or busy and not available to come to a visit.

Ask questions. Tell the study doctor and team if you don't understand something or you are worried about any of the assessments.

Bring personal items. Pass the time at visits by reading a book or magazine, listening to music, or watching a video. Please remember to bring your headphones if you will be listening to something.

Take notes. Keep track of questions you may have so that you remember to ask them.

eDiary

An eDiary similar in size to a mobile phone will be provided for your use while you are in this trial. The study team will show you how to use the eDiary to:

- Rate your average daily knee pain
- Rate your worst daily knee pain
- Record your paracetamol/acetaminophen intake

You will use the eDiary each day from the start of the run-in through to the end of the trial. The study doctor and team will review your eDiary compliance at each visit. You will also complete questionnaires at some visits.

Your responsibilities as a participant

While you are in this trial you will have some key responsibilities. For example, you will need to:

- Follow instructions from the study doctor and team
- Come to your study visits and complete the scheduled activities
- Receive injections of the study drug or placebo as assigned
- Complete daily eDiary entries
- Take only the pain medication provided by the study doctor
- Report any changes in your health
- Talk with the study doctor before taking any new medications

Schedule of activities

The study doctor and team will review this schedule with you. They will explain the activities and answer any questions you may have.

	Screening/Run-in		Study Treatment																		Follow-up		
	Screening[1]	Run-in[2]	Day 1[3]	*	Weeks 1, 2	Week 3	Week 4	Weeks 5, 6, 7	Week 8	Week 9	Week 10	*	Week 11	*	Week 12	Weeks 13, 14	*	Week 15	*	Week 16[3]	Weeks 20, 24[4]	Week 31[3]	Early stopping[3,5]
Informed consent																							
Full physical exam																							
Daily pain score																							
Medical history																							
Study treatment			← The study doctor will explain the study treatment schedule to you. →																				
Accurate pain reporting summary																							
eDiary training																							
eDiary entries		← Daily (average knee pain score, worst knee pain score, paracetamol/acetaminophen taken) →																					
eDiary review																							
Questionnaire(s)								Week 6															
Brief physical exam																							
Vital signs																							
ECG																							
Knee x-rays																							
Pregnancy test[6]																							
Blood samples				[7]				Week 6				[7]		[7]		Week 14	[7]		[7]				
Urine sample								Week 6								Week 14							
Tuberculosis test																							
Tobacco use review																							
Side effects review		← Continuous →																					
Medication review		← Continuous →																					

1 All screening assessments must be completed within 42 days prior to Day 1, except informed consent, which can be completed earlier.
2 The run-in period starts 7 days (1 week) before Day 1. You will need to stop taking your current pain medications before this.
3 You will need to fast for a minimum of 10 hours before this visit. "Fast" means not eating or drinking anything except water.
4 If allowed at your location, you may have the option for visits at Weeks 20 and 24 to be done at your home. The study doctor will tell you if this is an option for you.
5 If you stop study treatment early, you will be asked to complete the remaining visits and assessments (except for study treatment and post-dose blood samples). However, if this is not possible you will be asked to complete assessments at the Early Stopping visit and a final follow-up visit approximately 16 weeks after your last dose.
6 Pregnancy tests will be done for women of childbearing potential only.
7 Post-dose blood samples will be collected either 24–72 hours OR 96–120 hours after study treatment administration at the preceding visit.
* If allowed at your location, you may have the option for these visits to be done at your home. The study doctor will tell you if this is an option for you.

Your notes

Your notes

At GSK, we appreciate your consideration of this clinical trial as part of your journey. We look forward to the day that we can share the findings with you. Thank you for your time and your commitment.