Do you have myelofibrosis?

Learn more about a clinical study.
What Is a Clinical Study?
A clinical study is a way to evaluate a drug in people with a certain illness. Some clinical studies (or “clinical trials”) investigate drugs that doctors cannot yet prescribe.

A goal of a clinical study is to learn if a “study drug” is safe and effective for people to take. Effective means it helps in some way to use the study drug for a certain disease or condition.

To learn more about clinical studies in general, refer to https://www.fda.gov/ForPatients/ClinicalTrials/ucm407821.htm.

What Is This Clinical Study About?
In this study, 2 drugs will be studied together. One of the study drugs is an investigational drug. This means the drug is not approved by the US Food and Drug Administration for use in myelofibrosis (MF).

Incyte, the company that developed the study drug, is the study sponsor. Among other things, the study will examine

- If your spleen size is reduced
- If your MF symptoms are reduced
- What the side effects are when taking the 2 study drugs together

Talk to your doctor if you are interested in participating in this study.
To find a study center near you, call 855-463-3463, then select option 1.
You can also visit clinicaltrials.gov and enter NCT02718300 to learn more.
How Do I Know if I Qualify for the Study?

**INCLUSION CRITERIA**

Every study has guidelines to help determine if a person is eligible to take part or not. **Inclusion criteria** are all the things that must be true for you to join a study. For this study, some of these include:

- You must be at least 18 years old
- You must be diagnosed with MF
- You must be currently taking ruxolitinib for a certain period of time at a certain dose
- You must have an enlarged spleen, despite treatment with ruxolitinib
- You must have had a bone marrow biopsy or be willing to undergo a bone marrow biopsy

**EXCLUSION CRITERIA**

**Exclusion criteria** are all the things that would prevent you from joining a study. For this study, some of these include:

- You are taking or have taken another study drug for MF in the past 6 months
- You are unable to swallow food or pills
- You are unwilling to undergo a blood transfusion
- Your liver function, kidney function, or blood cell counts do not meet study criteria

To find out if you can be in the study, call this number:

**855-463-3463**, then select option 1. You may have to answer some pre-screening questions.
What Else Would I Need to Do if I Want to Join the Study?

You will need to get a complete physical exam to see if you are eligible for the study. During that screening, you may need to

- Give blood and urine samples
- Have a bone marrow biopsy if you have not had one before

How Long Will I Be in the Study?

You may be in the study for up to approximately 24 months.

What Will Be Expected of Me During the Study?

Throughout the study

- You will need to take all study-related drugs as instructed
- You will get regular checkups and visits with the study team
- You will have at least 12 lab visits for blood work or other tests
- You will need to have a bone marrow biopsy every 24 weeks while participating in the study

* A study team will stay in close contact with you to see how you are feeling and answer any questions you may have. 

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What Costs May Be Covered During the Study?

The study drugs will be provided at no cost to you. Your health plan may cover costs for your routine medical care. The study team may help you check with your health plan and your doctor about any costs related to the study. You will not be paid for being in the study.

You should learn before joining this study

- Which part of the research-related care will be free
- Which costs your insurer will pay; which costs you will have to pay
- If you will be reimbursed for travel costs up to a certain amount per visit

Are There Benefits and Risks to Being in This Study?

Your current doctor who is managing your MF is the best person to help you understand the possible benefits and risks of joining this study.

Below are 2 websites that can help you start a conversation

- https://www.nhlbi.nih.gov/studies/clinicaltrials/benefitsrisks
- https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics

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You may have to answer some pre-screening questions.
Is There a Study Center Near Me?

Review the map to find the study center nearest to you. To get the address and phone number of a study center, call the number below. You can also visit clinicaltrials.gov and enter NCT02718300 to learn more.

To learn more about this clinical study, call 855-463-3463, then select option 1.

You can also visit clinicaltrials.gov and enter NCT02718300 to learn more.