



CeleBr^{ate}

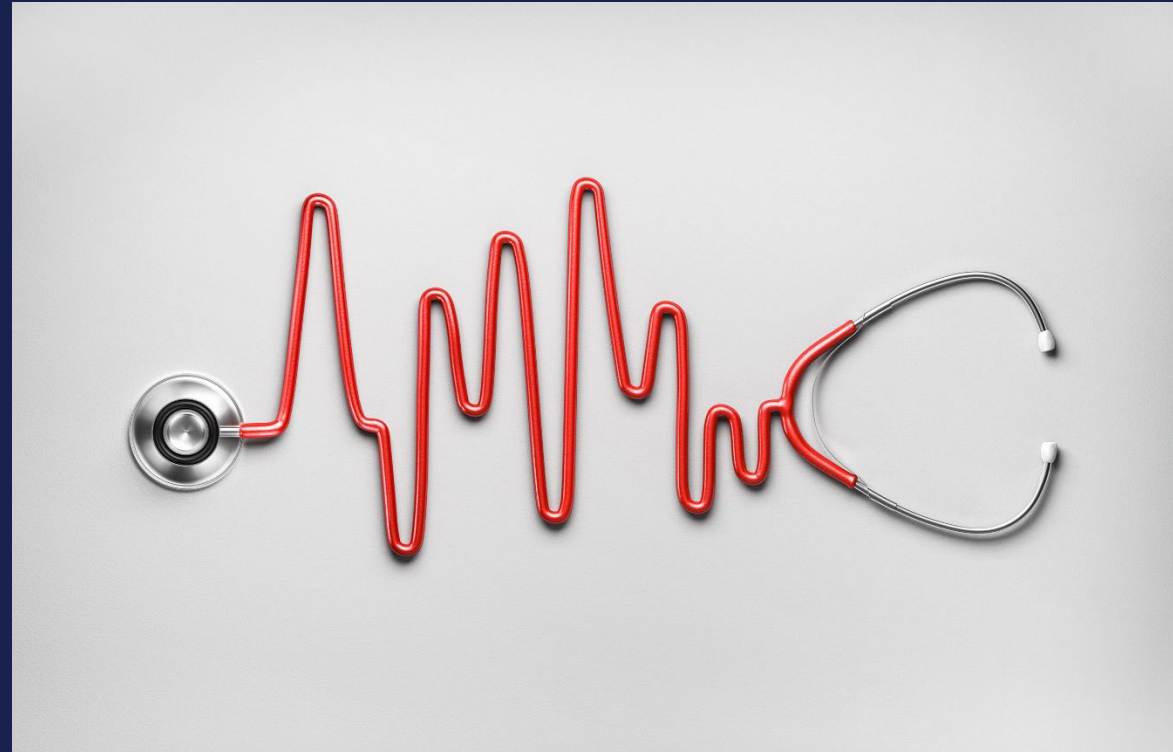


Presentation

December 2022

CeleCor
THERAPEUTICS

Welcome



Introduction

Local Principal Investigator

Jon McDonagh MD

Sub-Principal Investigator

Michael Levy MD

Study Team Members

Louise Cardenas (PAMC) Andrea Castelblanco Pardo PAMC
K Kelly (Ak Heart) Ben Lewis (AFD)

Facts About Heart Attacks In the US

800,000
heart attacks
occur each
year

It can take
1 hour+
to get to the
hospital

50% of
heart-attack
deaths occur
prior to reaching
the hospital



What is CeleBrate ?

CeleBrate is a Phase 3 prospective, blinded, randomized, placebo controlled, multicenter study to assess the safety and efficacy of a single injection of zalunfiban in subjects with ST-elevation myocardial infarction (heart attack) before patients arrive at the hospital.

Key Terms

Phase 3 trial

In a Phase 3 study/trial, the investigational study drug is given to large groups of people. Researchers assess its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the investigational drug or treatment to be used safely.

Investigational drugs

Medications that have been approved by the FDA to be tested in patients and other individuals but not yet available for sale.

FDA Approved drugs

Medications which have been studied and reviewed by the Food and Drug Administration (FDA) and determined to provide benefits that outweigh the risk of taking them for individuals who need them. These medications are commercially available meaning they can be sold to patients.

Blinded Study

A type of study in which the participants (single-blinded) or the participants and their doctors (double-blinded) do not know which drug or treatment is being given.

Randomization

A study in which the participants are divided by chance (like the flipping of a coin) into separate groups that compare different treatments or interventions. Using chance to divide people into groups makes it likely that the groups will be similar and that the effects of the treatments they receive can be compared more fairly.

Placebo

An inactive substance or other intervention that looks the same as, and is given the same way as, an active drug or treatment being tested. The effects of the active drug or other intervention are compared to the effects of the placebo. Placebo-controlled refers to a clinical study in which the control participants receive a placebo.

Multi-center clinical trial

A clinical trial that is carried out at more than one medical institution or research site.

Platelet

Tiny, disc-shaped pieces of cells that are found in large numbers in a person's blood or spleen. Platelets help to form blood clots to slow or stop bleeding and help heal wounds. Platelets will bind together when they recognize damaged blood vessels.

Platelet inhibitor

Also called anti-platelet drugs, platelet inhibitors work in different places where clotting occurs and prevents platelets to adhere or attach. Aspirin is the most commonly used antiplatelet drug.

Clinical Study

A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies:

- Clinical Trials (also called interventional studies)
- Observational Trials

What is a Clinical Trial?

In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the investigators.



Research Plan

Interventions may be medical products (drugs or devices), procedures, or changes to participants' behavior (such as diet).



New Medical Approach

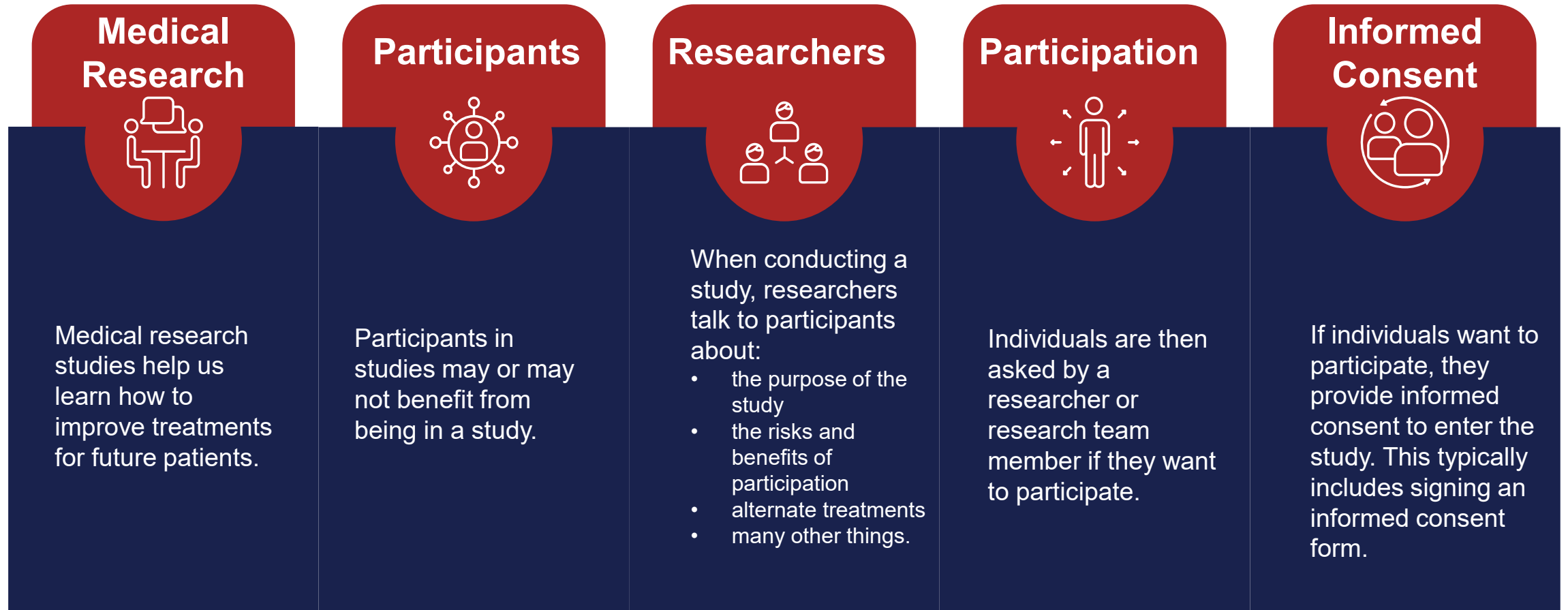
Clinical trials may compare a new medical approach to a standard one that is already available, to a placebo that contains no active ingredients, or to no intervention.



Comparison of Interventions

Some clinical trials compare interventions that are already available to each other.

How Does Informed Consent Typically Work in Clinical Trials?



Exception From Informed Consent (EFIC)

EFIC Clinical Trials

EFIC clinical trials are a special type of research study in which patients may be unable to provide informed consent to be in the study because of their condition and the need to get treated quickly.



CeleBrate

CeleBrate is an EFIC clinical trial and has been approved to proceed by the Food and Drug Administration (FDA).

What is Special About EFIC Trials?

Medical Emergency

EFIC trials are studies to learn about how to best care for patients having a medical emergency sometimes.

Unable to Consent

EFIC clinical trials involve participants who are unable to provide informed consent.

Family Member

If a family member or other representative is available, they may provide permission for the patient to be in the study.

Treatment

If a representative is not around to provide permission and the study medication must be given immediately, a patient can be included in an emergency study without anyone giving consent.

EFIC

This process is called Emergency Exception from Informed Consent or EFIC and is a special category of FDA approved research

When Can EFIC Be Used?

EFIC can only be used:

**when patients are
in life-threatening
situations**

**when prospective
informed consent
from the patient is
not possible**

**where the current
treatments are
unproven or
not good enough**

**when the study has
the potential of
direct benefit to the
participants**

EFIC clinical trials must also receive special approval from the FDA to go forward.

The
CeleBr^{ate}
Study



The CeleBrate Study

The CeleBrate study will enroll individuals who have a STEMI heart attack (a special type of heart attack) before they reach the hospital.

800,000

There are 800,000 heart attacks in the US per year

150,000

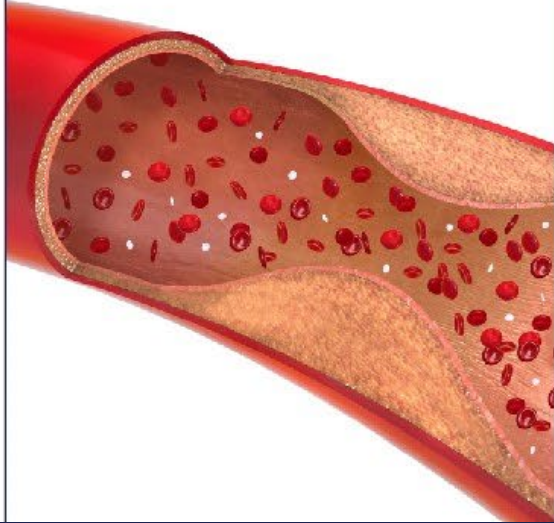
150,000 are STEMI heart attacks – a very serious type of heart attack

50%

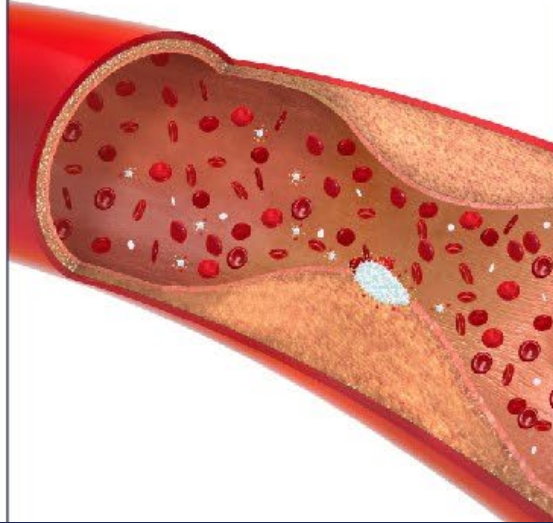
of heart attack deaths occur before a patient reaches the hospital

STEMIs are also called a ST-elevated myocardial infarction.

Normal Blood Flow



**Plaque Rupture
Platelet Adhesion
Release of Activators**



**Clot Formation
No Flow**



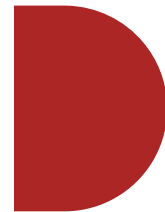
Take a Closer Look



The CeleBrate Study



The CeleBrate study is being done to study the effects of an investigational drug called zalunfiban which is being developed by CeleCor Therapeutics.



Early treatment for a heart attack is critical.

About Zalunfiban

Zalunfiban

Is the investigational drug used in the CeleBrate study and is a fast-acting platelet inhibitor.

Platelet inhibitors

Prevent platelets from adhering to each other and may reduce the chance that a harmful blood clot will form blocking blood to your heart by preventing the platelets from clumping limiting the size of the heart attack.

The CeleBr^{ate} Study

Heart Attack

Participants in the clinical trial will be enrolled by EMS before arriving at the hospital. If enrolled, you will have a 2 out of 3 chance of receiving the study drug.

Hospitalization

During your hospital stay, you will have additional blood drawn for research purposes. We want to test how the investigational drug works.

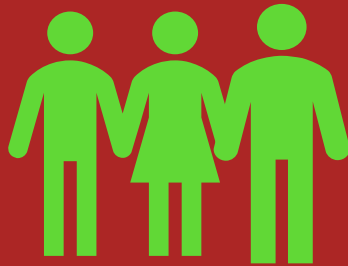
After the Hospital

The study team will contact you at 30 and 90 days after you have been released from the hospital. They will contact you again in 1 year.

Only patients who have a STEMI heart attack will be enrolled in the trial.

The CeleBrate Randomization Schedule

2 out of 3



Participants will be randomly assigned to receive zalunfiban.

1 in 3



Receives lower dose of zalunfiban

1 in 3



Receives higher dose of zalunfiban

1 in 3



Receives placebo

The CeleBrate Study

Participants in the clinical trial will be assigned by chance to receive one of two dose levels of zalunfiban or a placebo

2 out of 3

Two out of three participants will be assigned to one of the 2 doses of zalunfiban

1 out of 3

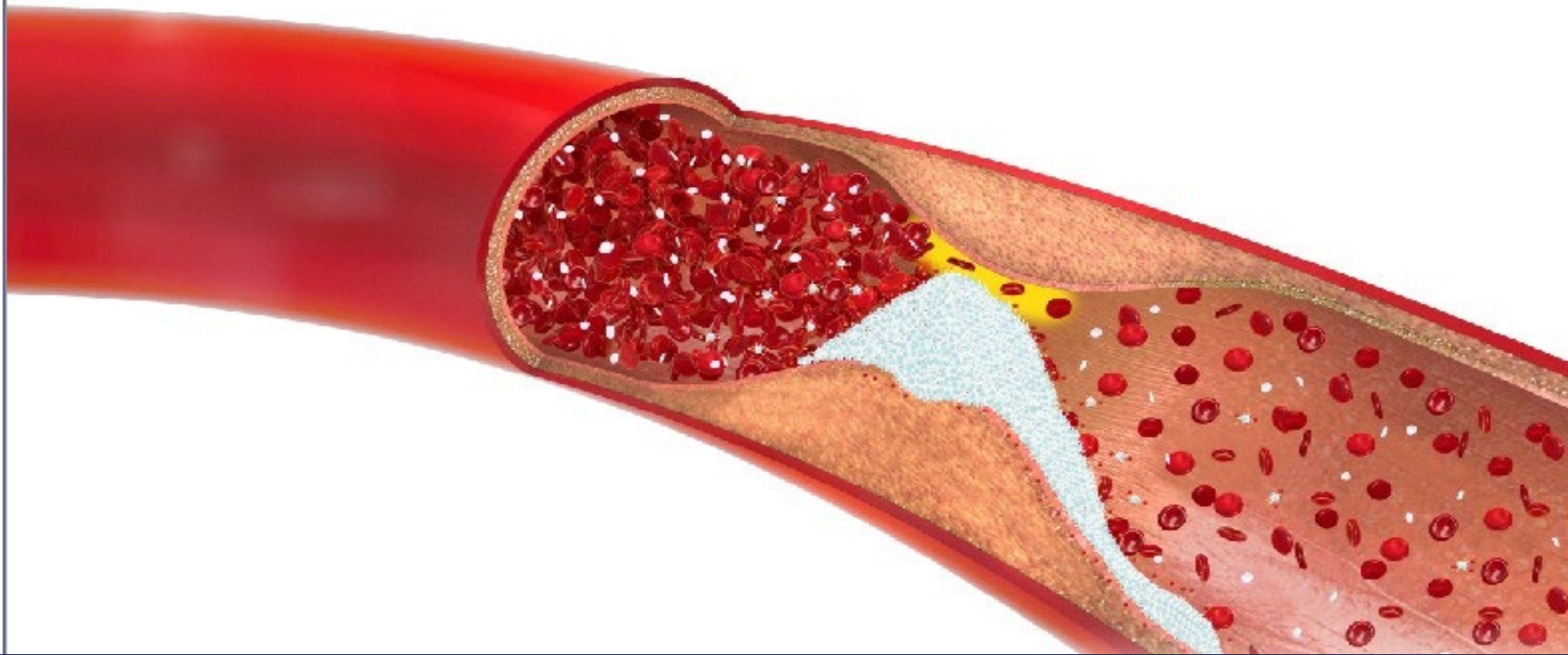
One of three participants will be assigned to receive placebo

Either the study drug, zalunfiban, or placebo will be given as a shot under the skin.

Will The Study Impact the Patient's Care?

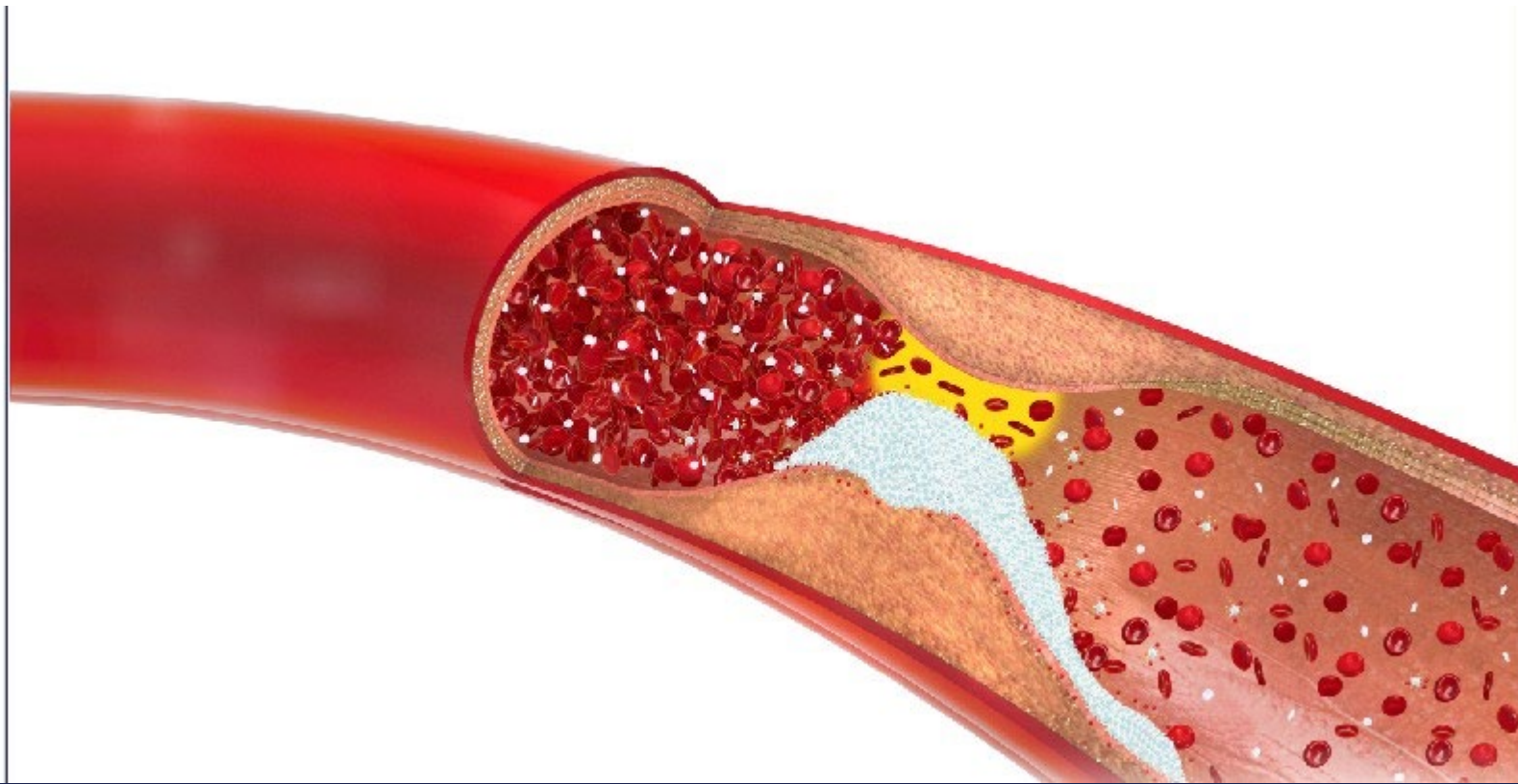
Answers

- ✓ No
- ✓ All participants will receive standard treatment for their heart attack
- ✓ Standard treatment may include aspirin, heparin or an FDA-approved platelet inhibitor
- ✓ Zalunfiban or placebo will be given in addition to the standard treatment



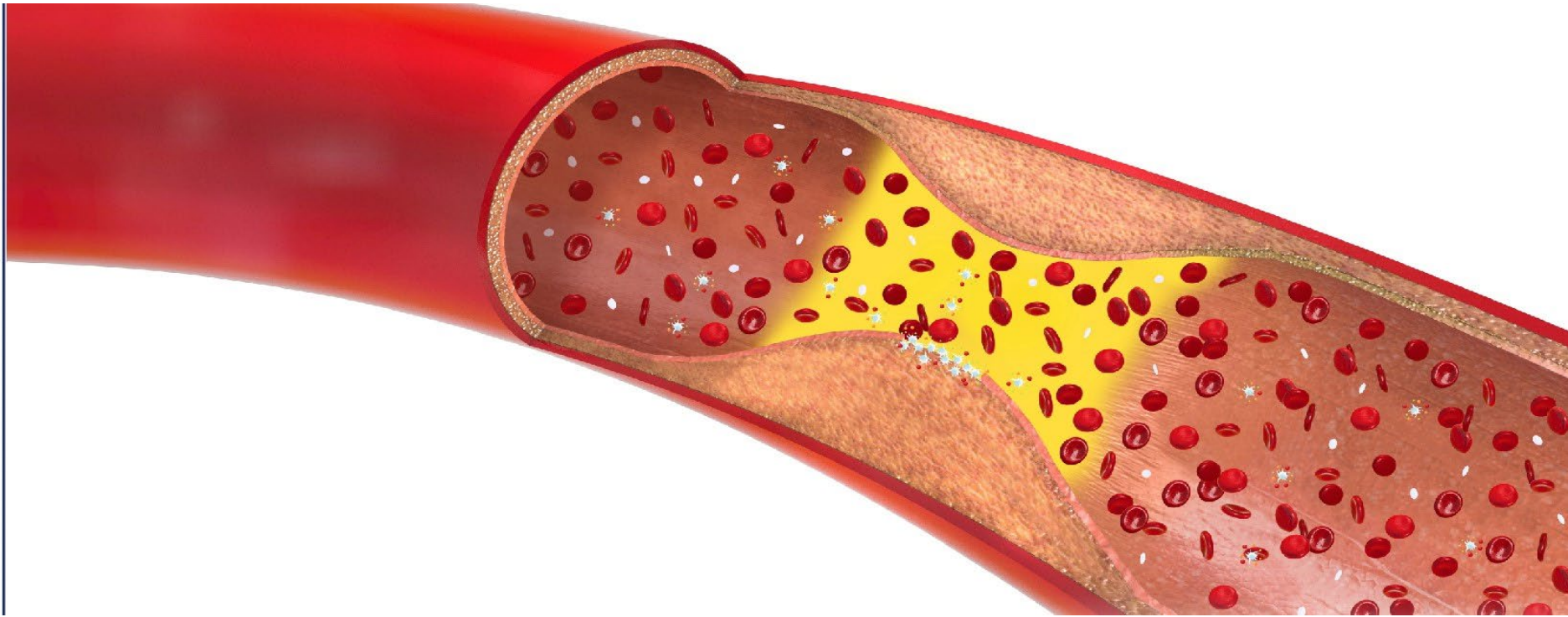
**Use of Aspirin
alone slightly
increases blood
flow.**

Standard Care



Use of a non-aspirin platelet inhibitor alone will moderately increase blood flow.

Standard Care



In pre-clinical tests, zalunfiban resulted in nearly normal blood flow.

Zalunfiban

Study Related Procedures



Blood

To determine the safety and impact of zalunfiban, additional research blood samples will be collected while the patient is in the hospital (about 4 teaspoons).



Follow Up

The study doctors will check on participants for one year after they are enrolled in the study to see how they are doing.

The CeleBr^{ate} Study

What are the Risks of the CeleBrate Trial?

Giving participants zalunfiban may lead to:

Bleeding

an increased risk of bleeding

Thrombocytopenia

a deficiency of platelets in the blood

Discomfort

bruising, bleeding, swelling or discomfort at the site where the drug is given

There may be other risks that are unknown at this time.

The collection of blood samples throughout the hospital stay may cause pain or bruising.

Can I opt out of participating?

Answers

- ✓ You can receive a wrist band that indicates your decision to not participate.
- ✓ If you live in the area where the trial is being conducted, you must wear the wrist band at all times while the trial is ongoing.
- ✓ You can call and obtain an opt out wrist band from the local study team.

Can I opt out of participating?

Answers

- ✓ To obtain an opt out wrist band, you can email CeleCor, the study sponsor, at celebrate@celecor.com
- ✓ You can tell EMS that you do not want to participate.
- ✓ You can tell your family members that you do not want to participate.

Community Consultation



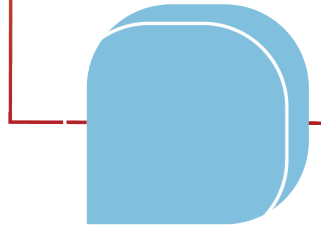
Community Consultation

- ✓ You all are participating in this discussion today as part of the “Community Consultation” process that occurs before the study can be approved by an ethics committee, or Institutional Review Board (IRB).
- ✓ Community consultation is required by the FDA for EFIC trials to take place in local communities.
- ✓ Researchers want to hear from you to learn about your opinions and reactions to the study.
- ✓ Information received from this discussion and your impressions of the trial will be presented to the study’s IRB.
- ✓ An IRB has the authority to approve the study to move forward or not.

Questions



Thank You



CeleCor
THERAPEUTICS