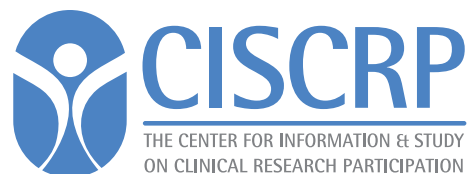




What is a Placebo and Why Are Placebos Used in Clinical Trials?

If you or someone you know is considering taking part in a clinical trial, this brochure is for you. It is intended to help you understand what 'placebos' are, and why they are used in clinical trials.

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HELPING YOU TO
MAKE AN INFORMED CHOICE

What is a Placebo?

A placebo is an inactive treatment, sometimes called a 'sugar pill.' In fact, a placebo may be in a pill or tablet form, or it may be an injection or a medical device. Whatever the form, placebos often look like the real medical treatment that is being studied except they do not contain the active medication.

CISCRP is not involved in recruiting patients for clinical studies, nor is it involved in conducting clinical studies.



Why are Placebos Used?

Using placebos in clinical trials helps scientists better understand whether a new medical treatment is safer and more effective than no treatment at all. This is not always easy because some patients get better in a clinical trial even when they don't receive any active medical treatment during the study. This is called the 'Placebo Effect.'

Because of this 'Effect', some volunteers who receive a placebo improve because of psychological reasons. Some volunteers feel better in a clinical trial because they are receiving a lot of care and attention. Also, some volunteers report having a reaction to the medication that they're receiving during a clinical trial – yet they actually received a placebo. In order to best determine whether a new medical treatment is safe and effective, researchers need to rule out the impact of the Placebo Effect.

Remember: The choice to be in the clinical trial is yours. At any time, if you have concerns about your clinical trial, you can speak with the doctor or study staff. Also, you will be notified if any new information comes available during the course of a clinical trial that might change your decision to participate.

How are placebos used in clinical trials?

Placebos have been used in clinical trials for a long time and they have played an important role in the development of many medical treatments. Placebos are used in different ways:

- Sometimes, one group of volunteers receives a placebo and another receives the study medication, but neither the volunteers nor the doctors know who has received placebo and who has received study medication.
- Some studies include a group of volunteers who take a placebo, while other volunteers take the new medical treatment, and still others take a treatment that is already on the market.

Some other facts about placebos:

- Placebos are not used in clinical trials where volunteers will be harmed if they do not receive a real medical treatment for their condition.
- Whenever a placebo is used, study volunteers will be informed before they agree to take part in the study. Volunteers who receive a placebo get the same attention, monitoring, care, and follow up as volunteers who receive an active treatment.
- The Food and Drug Administration may require a placebo to be used in order to prove that a medical treatment is safe and effective.

Will I receive a placebo?

Volunteers are often “blinded” as to which treatment group they are in, meaning they are not told what treatment they are being given until a clinical trial is over. So, you will not know if you are receiving the study drug or placebo during the trial. Using this approach, there is less chance of bias from study participants who know which treatment they have received.

Likewise, in most cases, the doctor and study staff themselves are blinded as to which volunteers are receiving the study drug or the placebo. This helps reduce possible bias that could affect the results of the research.

Whether or not you receive a placebo, you will be monitored very closely during the clinical trial. If there is a change in your medical condition while you are participating in the clinical trial, the research staff will inform you immediately and discuss the situation with you. They may recommend that you drop out of the clinical trial or they may recommend that you receive an active medical treatment.

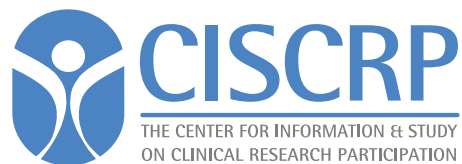
For answers to additional questions,
visit our web site at www.CISCRP.org or
call 1-877 MED HERO.

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CISCRP is an independent non-profit organization dedicated to engaging the public and patients as partners in the clinical research process through education and outreach programs. CISCRP services also assist clinical research stakeholders in understanding public and patient attitudes & experiences in research to improve patient satisfaction. *CISCRP is not involved in recruiting patients for clinical trials, nor is it involved in conducting clinical trials.*

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