Reproductive Facts

Patient fact sheet developed by the
American Society for Reproductive Medicine

Understanding clinical studies

What are clinical trials?

Clinical trials are research studies that test the safety and effectiveness of new treatments (new drugs, devices, or procedures). Health-care providers find patients with specific health problems, have them take different treatments, and see if the disease improves or not. All clinical trials are reviewed by special committees called institutional review boards (IRBs) to make sure that the trials are safe and ethical.

People often hear about research that claims that a particular treatment helps to treat a particular disease. Then the next day they may see a research study that claims the opposite. Which studies can you believe? This information sheet will help you understand these studies just a bit better.

How do they get the information?

Retrospective collected information (or data).
Researchers collect their information; retrospectively when they look backwards in time. Usually this means looking back at medical charts to try and find reasons for a problem after they find the problem. An example would be finding that a patient in a hospital got very sick with high blood pressure after eating a jelly bean. The researcher might wonder if jelly beans are toxic, and so they would go back through the charts of all the patients that ate jelly beans in that hospital and see if they got sick. But what if a bunch of patients ate jelly beans that were snuck into the hospital, so that information would not be in the chart. What if a whole bunch of people that ate jelly beans in the hospital got really sick, and they were all suing the hospital, but the lawyers took all those charts and put them in their office so the researchers didn't have access to them. What if the jelly beans only caused a few people to get high blood pressure in 1998, but the researchers didn't go back further than 1999 when looking at the charts. All of these examples show that retrospectively collected data have built-in errors, and aren't as reliable as prospective studies outlined next.

Prospectively Collected information (or data).
With this type of data collection, researchers have an idea that a certain treatment causes a disease. They will set up the study ahead of time, to make sure that all the people enrolled in the study are similar in age, weight, and genetics, and gender, and underlying medical problems. Then they would give them the treatment, and follow all of them for a time, then check and see how many people got the disease. Our example would be the toxic jelly bean. They would enroll people in the study, and make sure some weren't very overweight, or very tall, or were from the planet Vulcanalia where the genes are known to be different from humans, and they had very few medical problems. They would give them jelly beans, then check on them every few months for a set period of time, say 2 years. Then they would look at how many people got high blood pressure. They wouldn't be missing anyone's chart or information, because they followed every single one that was enrolled in the study. You can see how this type of data collection would be more reliable.

What are the best and most accurate studies?

- **Randomized controlled trials**
  The randomized, blinded, placebo controlled trial is the best quality study , because it is prospectively collected data, and randomization is used to decide who gets the treatment and who doesn't. The researchers then follow all of the people they enrolled, and find out if there really is a difference in outcome with the treatment. Our researchers now have a new idea about jelly beans. They think that eating fruit flavored jelly beans will help people that have high blood

pressure get lower blood pressure. So, they enroll all of the patients in their hospital that have high blood pressure. They decide that some people will get jelly beans, and some will get placebo, or things that look like jelly beans but only have sugar in them, not the fruit flavoring in real jelly beans. The researchers make sure that patients get put into the real jelly bean group, or the fake jelly bean group by using a random number, so that a certain researcher doesn't get to put all his friends that only have mildly high blood pressure into the jelly bean group. This makes sure that the groups have similar ages, weights,genetics,heights, and similar underlying medical problems. Then they follow all of the patients, no one knowing for sure if they got treatment or not. At the end of the trial, a different researcher would "unblind" the study and e information and find out if real jelly beans truly did lower blood pressure. This study is by far the best type of study, and these will be the majority of the studies that your health care providers will rely upon.

- **Cohort studies**
  These studies still use information that is collected prospectively, but the patients or their doctors decide what treatment they are going to get. The researchers use statistics to account for the patients having varying heights and weights and genetics and underlyinmedical issues, so they all get enrolled, then followed for a certain period of time, and all of the data is collected at the end. With our example, all of the patients get enrolled at the beginning of the study, but the patients and/or their doctors decide if they will be eating jelly beans or not. At the end of the study, they lookat the outcomes to see if the high blood pressures were lower with jelly bean treatment. Although not as good as a randomized controlled trial, this type of study is still a good one.

- **Case-control studies**
  Case control studies are a form of retrospective studies: The researchers use the medical records of people who already have a certain disease, then look at the charts to see if those people were exposed to a certain "treatment" or jelly bean. In our example, a researcher would review the charts of people with high blood pressure (cases) and see, for example, if they ate jelly beans. They would also review the charts of people without high blood pressure and see if they also ate jelly beans. As in the example above, information about jelly bean eating may be missing, so the information collected may be inaccurate. Although these types of studies are not as good quality as a randomized controlled trial, sometimes they are helpful as we begin to try and figure out the relationship between a disease (high blood pressure) and an exposure (r jelly beans).

How about the number of people involved in the study, does that make a difference?

In any type of clinical study, the number people studied is very important. It is best to have large numbers of study subjects. This helps show whether any difference is real or just a statistical fluke. For instance, studying 10 people who smoke may show no more cases of lung cancer than in a control group of 10 nonsmokers. This small group does not have enough subjects to show whether lung cancer is caused by cigarette smoking. Before the study starts, calculations should be used to figure out the number of subjects needed to show a true result. Often, several research centers may work together to find a large enough number of study subjects.

It is important to understand that not all studies are created equal. If you see a study and have questions about the quality of the study, ask your healthcare provider about the information. Chances are they have seen the study but may be able to better interpret the findings for you.

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