The significance of clinical trials

Jill M. Novitzke, RN

Zeenat Qureshi Stroke Research Center,
University of Minnesota

Abstract

Background: Clinical trials are essential for the development of new treatments. Whether a person should participate depends on their understanding of the risks and benefits for themselves and for society as a whole.

Discussion: There are rules in place to protect human research subjects and all studies involving humans are reviewed locally to ensure that subjects are treated safely, fairly, and confidentially. Nevertheless, each subject should consider for themselves whether participation is consistent with their values.

Conclusion: Clinical trials, when well-designed, can benefit the participants as well as the investigators, the sponsors, and the medical community.

Keywords: clinical trial, research

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Every new medicine and treatment started with volunteers participating in clinical trials. We owe our current high standards of medical care to studies that have been conducted in the past under guidance of the US Food and Drug Administration (FDA). In addition to testing new drugs and devices, clinical trials provide a scientific basis for advising and treating patients. Even when researchers do not obtain the outcomes they predicted, trial results can help point scientists in the correct direction.

Physicians play a key role in referrals to clinical trials. Being well-prepared to answer the following common questions will help clinicians guide their patients and family members through the decision process.

Why participate in a clinical trial?

Well-designed and executed clinical trials provide an opportunity for participants to:

- Play an active role in their own health care
- Gain access to new research treatments before they are widely available
- Increase the options for treatment when standard therapy has failed
- Obtain expert medical care at leading health care facilities during the trial
- Help others by contributing to the advancement of medical knowledge

Are clinical trials safe?

The FDA works to protect participants in clinical trials and to ensure that people have reliable information as they decide whether to join a clinical trial. The FDA has regulations for clinical research to protect participants from unreasonable risks. Although efforts are made to control the risks, some may be unavoidable because of the uncertainty inherent in medical research studies involving new treatments.

In addition to FDA oversight, every clinical trial in the US must be approved and monitored by an Institutional Review Board (IRB) to make sure the risks are as low as possible and are worth any potential benefits. An IRB is an independent committee of physicians, statisticians, community advocates, and others that ensures that a clinical trial is ethical and the rights of study participants are protected. All institutions that conduct or support biomedical research involving people must, by federal regulation, have an IRB that initially approves and periodically reviews the research.

Researchers are required to give prospective participants complete and accurate information about what will happen in the trial. Participants must sign an "informed consent" document indicating they understand that the trial is research, and that they can leave the clinical trial at any time. This informed consent is part of an ongoing process that ensures a prospective participant in a clinical trial understands what known risks might be associated with the study.

Some examples of possible risks in clinical trials include:

- unpleasant, serious, or even life-threatening side effects resulting from the treatment.
- treatment may not be effective for the participant.
- greater time and attention investment than standard treatment.

What else should be considered before participating ?

People should know as much as possible about the trial and feel comfortable asking the members of the health care team about it. The following questions might be helpful for the participant to discuss with the trial team:

- What is the purpose of the study?
- What kinds of tests and treatments are involved?
- How do the possible risks, side effects, and benefits in the study compare with my current treatment?
- How might this trial affect my daily life?
- How long will the trial last?
- Who will pay for the experimental treatment?
- Will I be reimbursed for other expenses?
- Is long-term follow up care included in the study?
- How will I know the experimental treatment is working?
- Will results of the trials be provided to me?

Whether or not to participate in a clinical trial is a personal decision. Each patient and each clinical trial is different. When considering a clinical trial, a person should try to gather as much information as they can and then do what they feel is best in their own mind. Those who decide to volunteer may be contributing directly to our understanding of diseases and how to treat them.

Correspondent: *Jill M. Novitzke, RN; Department of Neurology, MMC 295; University of Minnesota; 420 Delaware Street SE; Minneapolis, MN 55455; USA; novit001@umn.edu*

Can I drive after my stroke?

Amy E. Puchta, RN

Minnesota Stroke Initiative,
University of Minnesota

Abstract

Background: Stroke can advesely affect movements, sensations, alertness, awareness, coordination, and judgement, all of which may impair the ability to drive a car.

Discussion: Many stroke patients consider driving to be essential to their quality of life and want to drive if at all possible. Thus, the physician may be challenged with a tough decision about whether a patient should be allowed to drive.

Conclusion: Referral to an occupational therapist can be of great help.

Keywords: stroke, driving

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Every year in the United States as many as 700,000 people suffer a stroke. Many of these people won't survive, some may recover with no obvious impairments, and others may be left with a wide range of disabilities. Those with disabilities will definitely benefit from acute rehabilitation. However, once a patient is past the acute rehabilitation aspect of their recovery the question often arises as to whether or not they may resume driving.

Driving is very important to people and provides them independence. Many stroke victims would find it hard to give this up. How do you decide if it is safe for someone to get behind the wheel of a car again? There is no simple answer but there are many resources available now to aid in making an informed, responsible decision.

Factors that affect driving after a stroke

The first thing to consider is what kind of stroke the patient had. The brain is divided into many areas and almost all of them influence movement and sensation. In driving many of these areas are used simultaneously and the effects of a stroke in any part of the brain may affect someone's ability to drive again. Driving is a very complex skill and may be greatly affected by any of the following deficits:

- Weakness, paralysis or numbness
- Neglect
- Visual impairment
- Diminished memory, judgment or concentration
- Slow reaction time

Patients may or may not comprehend that they have these impairments. If possible it is helpful to discuss with close family and friends the changes they have noticed in the patient. Family and friends have more opportunities to observe effects that may not be easily observed by the practitioner in a short clinic visit.

Resources to assess driving skill

It is a good idea to be familiar with the requirements of your state's department of motor vehicles for patients who have had a stroke. Each state has specific physical, sensory and cognitive requirements that each person must meet to be eligible for a driver's license.

An occupational therapist can provide a valuable comprehensive screening of a patient's current skills and deficits. From there a patient could be sent for further evaluation by a certified driver rehabilitation specialist (CDRS). They can assess driving skills in a controlled and safe environment. The patient is given a behind-the-wheel evaluation that will include testing for changes in vision, functional ability, reaction time, judgment and cognitive abilities. After this assessment the CDRS can determine if the patient is safe to drive, can not drive at all, or may drive with additional interventions. They may need to modify the car or use adaptive equipment. With or without special equipment, a patient may benefit from classroom training and simulation training. These are all services that a driver rehabilitation specialist can help with.

If your patient can not return to driving, be sure to encourage them to use public forms of transportation. This will increase their ability to be independent without the risk of driving themselves. Many communities also offer services to help patients that suffer from mobility problems.

For those who do return to driving, it is also important to understand the warning signs of stroke so that they are aware if any of them should occur again. This may help them get off the road and seek immediate medical help.

Conclusion

Whether or not to let your patient that has suffered a stroke drive is a decision not to be taken lightly. The patient is not only putting their safety at risk but the safety of those around them when they get behind the wheel. However, with careful, professional evaluation of specific skills, it is possible to make a well-informed decision about who can resume driving.

Correspondent: *Amy Puchta, RN; Department of Neurology, MMC 295; University of Minnesota; 420 Delaware Street SE; Minneapolis, MN 55455; USA; apuchta@umphysicians.umn.edu*