Debunking 8 Myths About Cancer Clinical Trials

No, patients on a trial are not ‘guinea pigs,’ says CU Cancer Center expert Bradley Corr, MD. Here are the facts.

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Clinical trials – a specialty of the University of Colorado Cancer Center – have brought new hope and longer lives to countless people with potentially deadly cancers. Most advanced cancer therapies in use today emerged from clinical trials.

And yet, misunderstandings about clinical trials – what they are and how they work – keep some people from accessing the life-saving treatments they offer.

Research shows that patient beliefs and mistrust about clinical trials are a key reason why some who might benefit don’t take part. A review of 20 years of studies of trial participation found that nearly half of cancer patients decline to take part in a clinical trial when offered the chance to enroll.

Often, people tell researchers they fear being “guinea pigs” for untested, possibly unsafe experimental treatments. Others worry they’ll be put in a control group with no treatment for their cancer.

To help us debunk myths and misconceptions about cancer clinical trials, we turned to CU Cancer Center member Bradley Corr, MD, associate professor in the CU Anschutz Department of Obstetrics and Gynecology’s Division of Gynecologic Oncology, where he’s director of clinical research, and is the inaugural holder of the Katie Taylor Memorial Endowed Chair in Gynecologic Oncology.

Corr has led numerous trials and is vice chair of a committee that facilitates early-phase clinical development of gynecologic cancer therapies at NRG Oncology, a national cancer clinical research organization.

Myth: Half the patients on a clinical trial get a placebo instead of any

treatment at all.

Fact: There are some trials for a new (novel) therapy that have a placebo group, but no clinical trial would ever have a placebo for a patient without also including the approved standard-of-care therapy. If there's a trial with a placebo, you're either getting the standard treatment along with the placebo or the novel agent being tested. It would be unethical to without treatment from a patient.

In any case, a patient is always advised in advance about the possibility of a placebo and can decide if it's not the right fit and they'd rather stay on standard therapy. But the reality is, many trials do not have placebos.

Myth: Clinical trials are only for really sick people.

Fact: That's absolutely not true. Some people think they should only go to a clinical trial when they've exhausted all standard-of-care therapies. In fact, many clinical trials incorporate the standard-of-care therapy and add on a novel therapy that's being evaluated as better than or at least equal to standard-of-care therapy. In those trials, the reality is that the healthier you are, the better clinical trial candidate you are.

Myth: Taking part in a clinical trial will cost me a lot of money.

Fact: Clinical trial costs are presented to the patient up front in a consent form. And the reality is, clinical trials are considered standard-of-care therapy under almost all insurances and Medicaid, so the patient should not incur any additional costs outside of their standard-of-care costs. Any extra imaging or evaluations within a trial that are not standard of care are billed to the sponsor of the trial.

For example, if a patient pays a copay for their CT scans, they'll still be required to pay their copay for CT scans in the trial. However, if they require an extra MRI that they normally wouldn't get, that would be billed to the study.

Under the federal Affordable Care Act, no health care plan can deny participation in a clinical trial, or limit coverage of routine patient costs related to a clinical trial, or deny out-of-network coverage if a clinical trial is not available within your health system.

Myth: Clinical trials are dangerous experiments.

Fact: No one wants to be a guinea pig. Providers never consider a patient a guinea pig. Our goal is always to put the patient first. I only present clinical trials to a patient that I think will possibly benefit them. It's an opportunity to receive the latest and greatest therapy that may not be available to other people yet.

There are a number of different phases in clinical trials. In order for any therapy to get to an early-phase human trial, there is an extensive amount of research done about potential side effects and efficacy, so we already know quite a bit about these drugs prior to any human ever getting them. And there's also careful evaluation of patients to make sure they can use the drugs safely.

In a later-phase trial, a drug will already have been given to a number of patients – typically hundreds across the country or the world – so we already know a lot about their side effects and what patients can expect on therapy.

Myth: I won't be told about any risks involved.

Fact: Potential risks are always discussed with the patient before getting any type of therapy. There's a pretty extensive conversation about what the potential effects are and how we mitigate them. That's also covered in the written consent form. We go over that with patients line by line and they get to keep a copy.

Myth: I can only get into a clinical trial if my doctor refers me.

Fact: Actually, we receive patient self-referrals all the time. The CU Cancer Center has an online site that's regularly updated, listing open clinical trials. It has email addresses and phone numbers for our nurse navigators who can help a self-referring patient.

Also, there's a wonderful national online resource called clinicaltrials.gov where a patient or provider can research available clinical trials nationwide, and you can find out if the CU Cancer Center is a site for a trial.

Myth: I won't be allowed to leave a clinical trial once I start.

Fact: In any therapy, a patient's autonomy is taken very seriously, and a patient can decide that they don't want to be the trial therapy anymore for any reason. Oftentimes that reason is side effects, or sometimes a patient just says, 'I'm tired of therapy at this point, I don't want to do this anymore.' That's absolutely within their rights, and they're never looked down upon. It's usually a conversation with the provider.

Myth: I don't need to go on a clinical trial to access new drugs because the government says I can have access to them.

Fact: That's a reference to the Right to Try Act, which deals with allowing access to certain drugs that have not been approved by the Food and Drug Administration. You have to have been diagnosed with a life-threatening disease or condition, which is almost always the case with cancer, and you have to have exhausted all approved treatments.

But there’s one more stipulation: The law also requires that you are unable to participate in a clinical trial involving the drug you want to try. So if we have a clinical trial on that drug, you would have to enroll in the clinical trial to access it.

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