Clinical Trials for Lung Cancer: What They Are and Why You Should Ask Early

Dr. Ashish Saxena (00:00):

Some trials are only available for patients when they first start their treatment and they're not an option after you've already started treatment.

Intro Voiceover (00:09):

Lung cancer is a tough topic. It's a disease that affects patients, families, friends, coworkers. But first, it's a disease that affects people.

Intro Voiceover (00:19):

Advances in lung cancer treatments over the last few years have made it possible to live with lung cancer for years after diagnosis.

Intro Voiceover (00:27):

The Hope with Answers Living with Lung Cancer Podcast brings you stories about people living, truly living with lung cancer. The researchers dedicated to finding new breakthrough treatments and others who are working to bring hope into the lung cancer experience.

Wendy Brooks (00:47):

Hello, I'm Wendy Brooks and I'm living with small cell lung cancer. And today we're taking a closer look at clinical trials, what they are, how they work, and why it's so important to ask about them early. To help us unpack all of this, we're joined here by Dr. Ashish Suksana, MD, PhD, Associate Professor of Clinical Medicine and Section Chief of the Thoracic Medical Oncology Service at Weill Cornell University. Dr. Suksana, what do you want patients and families to understand first about clinical trials?

Dr. Ashish Saxena (01:23):

Thank you so much for having me, Wendy. So I think one thing to really hammer home is that clinical trials are a vital part of getting better treatments to our patients. And so they're an important option for all our patients undergoing cancer therapies. And one of the things that's important is to ask about the availability of clinical trials immediately after you get a diagnosis, because some trials are only available for patients when they first start their treatment and they're not an option after you've already started treatment. So patients and families shouldn't assume that the conversation or decision about doing a trial can wait till later or for a second opinion, they should ask about it upfront.

Wendy Brooks (02:06):

Exactly. And a lot of people, they hear clinical trial and they get nervous. It's a scary term and one that carries some misconceptions.

Dr. Ashish Saxena (02:17):

Yeah. So people will often say to me, my patients will say, "Oh, is this like me being a guinea pig?" And so I think it's important to really emphasize that you're not a guinea pig. When a study or a trial or a drug gets to the point where we're giving it to patients, there's already some data that it's going to work. We're not just blindly saying, "Let's try this. " And then one of the misconceptions is that they're not going to get treatment, that they maybe get a sugar pill. And that's really not true in the vast majority of, especially cancer clinical trials, that you're not going to get anything. The times when that might happen is if there is no standard treatment and they're trying something new. You're generally going to get something that is part of a standard of care that you would have gotten anyway.

(03:02):

Sometimes for certain types of trials, the standard of care isn't really that good. And so you're getting something that we think is going to be better, but then in some other trials, you're getting a new drug that's added to what's the standard of care or the treatment that's already been approved because we want to see if doing something different or more will enhance the efficacy of the responses that we see. And so you're not really a guinea pig in that sense that we don't know what we're doing and we're just giving you something and who knows what will happen.

Wendy Brooks (03:32):

Yes. And that's so important. And I'm actually in my second clinical trial. And with my clinical trial experience, I've actually received better than the standard of care. And that is, I've received more frequent scans, more blood draws, more visits with my oncology team. And it actually gives me a better level of comfort knowing that this therapy is working.

Dr. Ashish Saxena (04:00):

Yeah. I think that's something I also tell my patients is when you're on a clinical trial, you will be watched closely all side effects, anything that's going on with you is going to be taken very seriously because you're on the study. So you often do get a lot more attention in a way than when you get the standard of care.

Wendy Brooks (04:18):

Absolutely. So it's really important that patients realize they're not giving up proven treatment by joining a clinical trial.

Dr. Ashish Saxena (04:26):

Yeah, absolutely. We don't want to give you something that we are like, "This isn't going to work, but we're just going to give it to you. " It's been through testing by the time it gets to you to make us believe that it's going to work. It's going to work and we're trying to see if it works better or worse or has more side effects, but we're not giving you something on a clinical trial that is sort of not proven at all. And in a lot of cases, as you mentioned, you're getting access to promising new options that will be the standard of care. So you get access to tomorrow's medicine today.

Wendy Brooks (04:58):

Absolutely. Well, now I have a three part question for you and we can break this down. Can you explain what happens during a clinical trial over time as the data comes back and the trial is either going to go well or not so well, right? And what would constitute a trial pivot and do these factors impact

Dr. Ashish Saxena (05:21):

Patients? Yeah. So you're right, especially in modern clinical trials, there's a lot of reevaluation primarily for safety, but also just for the efficacy of the drugs that are going on. So behind the scenes while you're on the trial, there are the study team, the sponsor of the trial, the doctors involved, we meet regularly and go over what's going on. And so we go over the results that we've been seeing, any side effects that have been going on. And if everything looks good, if nobody's having a lot of side effects and we're seeing good responses, then we may just continue as planned. But if on the other hand, we're seeing a lot of a particular side effect that we didn't think would happen, but it is, that would result in lowering the dose of the drug or doing something different or stopping it altogether because we're seeing something that we didn't intend to.

(06:13):

Or a lot of times we'll see that maybe this drug works really well in a particular type of patient, maybe a particular type of lung cancer or something about it. And we may say that, "Oh, we're going to now sort of focus on this type because this is where we're getting the most data." So that might change the clinical trial and we may focus on getting a particular patient because we know they're going to do really well. And then again, if there's no really good efficacy, then a lot of times the trials, what they do stop early, as they say, they have these periods where we stop a lot of times enrollment. So they'll be, "Oh, the study's open, but it's not enrolling right now," because everybody's looking at the data and saying like, "Hey, is this even working?" And if the comes back as this isn't working well, then the trial can stop early.

Wendy Brooks (06:59):

Oh, that's interesting. I've noticed that in the clinical trials that it was open, but yet that you weren't enrolling, but that's really what's happening with that trial is a reevaluation period.

Dr. Ashish Saxena (07:12):

Yeah. They have sort of like a data lock period where they get all their data, we have to hand in everything and then they get to look at the people running the studies to see if we need to make a pivot or something like that. Interesting.

Wendy Brooks (07:25):

Well, I've had to pivot from my first trial to my second trial. And what was interesting, there was a slight volume increase in my tumor, in my lung, and my PI had gotten permission from the sponsor to go ahead, let's hit that with some radiation and continue with the trial. So we thought that that was a really good option. However, in looking at how I was responding overall with adverse effects, I did have some ... Oftentimes I was getting frequent blood transfusions because my hemoglobin level was low. So it turned out that a pivot at that point to a different trial was actually the best course of action for me. And as it turns out, this new study therapy that I'm on has provided a better overall response to the cancer and actually to my blood chemistry, I'm not having to get those frequent blood transfusions.

(08:25):

In fact, if you were to look at my labs, you would think there's nothing wrong with her. So that really was the best move to make that pivot and actually go on to a different therapy.

Dr. Ashish Saxena (08:37):

Yeah. No, that's fantastic. And two things about that, what you mentioned. One, the idea that the PI was able to get radiation, which maybe wasn't part of the original part of the study, but for you to get that is another important thing. The trials aren't usually not so rigid. You can go back and say, "Hey, we have a special circumstance." And there's a process of getting approval and things like that, but these things happen where there's special circumstances and we need to do something a little different and they make sure that it's safe and it's in the patient's best interest, but they oftentimes will allow something that's a little off what was originally intended on the study because it's in the best interest of the patient. Exactly. Yeah. And then I also, with clinical trials, just like there is with the standard of care treatments, sometimes for a particular patient, some work better than others.

(09:26):

Like you mentioned, the first trial had more side effects and the second one had less. And the same thing is true with your standard treatment. Some patients respond better to one and then we say, "Well, this isn't working or you're having too many side effects and we'll try something else." And that one is the one that they respond better to.

Wendy Brooks (09:41):

Absolutely. And I know that criteria in getting into a trial, there are certain things that the patient must meet, but I do like the fact that once you're in it, that there is some of that flexibility within that trial, like you said, that you can't, it's not so rigid and we have to look at each patient as an individual and how they're responding, but also within the parameters of the trial itself.

Dr. Ashish Saxena (10:10):

Yeah, absolutely. The answer even on the trial is always like, let's just do what's best for the patient.

Wendy Brooks (10:16):

Absolutely. Well, and that's so important. Yeah, for sure. Thank you so much for your overview of these clinical trials. And I really want to call out a distinction between the small cell lung cancer and non-small cell lung cancer, because there's more of an urgency to explore clinical trials with one variation of lung cancer versus the other, correct?

Dr. Ashish Saxena (10:40):

Yes, for sure. Small cell lung cancer tends to be a little bit more aggressive and presents more likely to present when the cancer is spread. And so it is important to get on therapy quicker and also on the same vein to ask about clinical trials sooner and early on, because you definitely have to start some treatment usually quicker. So getting that information about the clinical trial upfront is really important, particularly for small cell patients.

Wendy Brooks (11:11):

Absolutely. Absolutely. It's just so important that someone that's diagnosed with small cell lung cancer, those clinical trials become all that more important, as you said, with it being so aggressive.

Dr. Ashish Saxena (11:24):

Yeah. But I think one of the good things in light of clinical trials is there's been so much advances in small cell lung cancer lately, all because of clinical trials, more so in the last couple years than probably in the last maybe 20 years before it or more, a lot has come out and they've all been through clinical trials, carefully done clinical trials that have really had amazing results that we didn't used to see with patients. So that's another reason why doing these clinical trials are important. A lot of immunotherapies and next generation immunotherapy drugs are now reaching patients through clinical trials first and then getting FDA approved and then becoming part of our standard of care. And so I lecture our students on small cell lung cancer, and in the past it's kind of been the same lecture over and over, but in the last couple years, I keep having to add more stuff and change stuff and teach them new things because so much has changed.

Wendy Brooks (12:19):

Keeping you on your toes,

Dr. Ashish Saxena (12:20):

Right? Yes, exactly. Yeah, which is a really good thing.

Wendy Brooks (12:24):

And that's so true because I was diagnosed with limited stage small cell in July of 2023. And at that time, the standard of care was really the best option for me, which was chemo radiation. But once I went into the extended stage of small cell with the brain metastases, my next best course of action as you stated, I wanted the medicine of tomorrow today and something that was going to give me longer progression-free survival and have less adverse effects. So that medicine, it gives me more time with my family and my friends enjoying the things that I like to do. And I'm just so blessed to have that opportunity to participate in these clinical trials and to have that medicine here now in the last two years that wasn't there when I was first diagnosed has been a godsend.

Dr. Ashish Saxena (13:21):

Yeah. That's amazing and so wonderful. And I definitely just, even with my patients, I just have more of them living like you with the small cell lung cancer, but doing great and doing their usual things and vacationing and spending time with their families now. And it's all because of the clinical trials that were recently done and either they're on a clinical trial now or something was approved because of a clinical trial that was going on before, and so their outcomes are so much better.

Wendy Brooks (13:47):

Okay. Another question we have for you today is, can you explain the difference between the clinical trials for limited stage small cell lung cancer and extensive stage small cell lung

Dr. Ashish Saxena (14:01):

Cancer? Sure. So in limited stage small cell lung cancer, the cancer is generally confined to the chest area, the lung and some lymph nodes. Basically our definition is if it's confined to a space that you can safely do radiation at once, and that would make it limited stage. And then so extensive stage is kind of anything beyond that where the cancer has spread, usually maybe to another organ like the brain or the liver or just in the other lung where it's not safe to radiate everything. So that makes it extensive stage.

And for clinical trials, sometimes with limited stage, we are trying to cure the cancer. And so a lot of clinical trials are about kind of things we can add to keep the cancer from coming back. Whereas for extensive stage, our goals are more to prolong life and have you living with the cancer and not having it give you the side effects from the drug or from the cancer itself.

(14:58):

So the goals are sometimes different of what we're looking at. A lot of the same drugs often will start out in extensive stage cancer and then we'll try to see how they work in limited stage in preventing cancer recurrence. So immunotherapy is a good example of that where we started these trials with extensive stage and then move them to trying it on patients with limited stage. There are a number of, as I kind of mentioned, new immunotherapy treatments like bispecific T-cell engagers, which are now FDA approved, but there's others also being studied. And then also trials, like we have one here where we're adding other things to the immunotherapy like VEGF inhibition to see if that also enhances beyond what we're standardly doing in patient survival.

Wendy Brooks (15:43):

Right. And having those options, as I've said before, are just so crucial to us as a patient. And that the trial that I'm in currently is a bispecific T-cell engager, and it's a subcutaneous injection, which hopefully will provide a little more flexibility for patients in the future and not having to be hooked up to an IV the entire time that you're receiving your treatment. So it's all great news.

Dr. Ashish Saxena (16:14):

Yeah, for sure.

Wendy Brooks (16:16):

Well, where can patients go to learn more?

Dr. Ashish Saxena (16:19):

So you can start by asking your doctor about clinical trials, but doctors don't have all the information all the time at their fingertips. So another place is to visit lcfamerica.org. That site can help patients learn about clinical trials that are currently enrolling and offer some guidance on questions that they can ask the doctors when they're considering a clinical trial to see if it would be a good fit for them.

Wendy Brooks (16:42):

Absolutely. Absolutely. And that's what we as patients are looking for. We're looking for that quality of life and let's see what we can do to help maintain that and control this cancer. So we definitely appreciate all the research that's going into this. We definitely talked about a lot today. What is one simple question patients should ask their doctor upon diagnosis?

Dr. Ashish Saxena (17:11):

So I think just asking upfront, are there any clinical trials available for my type of cancer that I might fit in with either at where they are or somewhere close by? A lot of us know of other clinical trials in the area, even if it's not at our own institution, but asking that question, you shouldn't assume that the doctor's going to know all of them and explain them all to you upfront because we often don't. We sometimes have to research them and sometimes I'll say, "Let me get back to you and ask around." But asking makes the doctor think about it also and bring it up. And for the patients, it's important that you have all these

options available. I usually, for a lot of the new patients I have, I'll go over options, but I'll make one option saying, and one option is clinical trials.

(17:56):

And I might say, "Well, I don't have one open here, but there may be others." Or, "I do have one open here, and I think it's a great option for you. " So asking upfront about clinical trials the first time you meet your doctor is, I think, a really good step in getting all your options put out there for you.

Wendy Brooks (18:13):

Absolutely. So what is the biggest takeaway that you want our listeners to remember?

Dr. Ashish Saxena (18:18):

So I think, again, clinical trials are really, really important. They are how we get our future medicines and you then have access to them today. And so ask about them upfront early, as early as you can. And again, sometimes they'll say, "No, there isn't one or there's one in Europe and you're not going to fly there." But at least knowing what the options are for your treatment is important. So asking upfront right away and understanding that clinical trials are important, they're part of a standard of care for cancers.

Wendy Brooks (18:54):

Absolutely. Well, Dr. Suksena, thank you so much for joining us on LCFA's Hope with Answers podcast.

Dr. Ashish Saxena (19:03):

Thank you. Thank you so much for having me.

Wendy Brooks (19:04):

Oh, you're so welcome. And as always, to learn more about lung cancer, please visit lcfamerica.org.