# The Octopus trial: Your questions answered – Transcript

00:04

My name's Jane and I was diagnosed with MS 11 years ago now. First of all, relapsing remitting MS and then a few years later onto a secondary Progressive and hence that's what's brought me here to the trial, the Octopus trial.

I used to be a teacher, but I live alone, I'm widowed now my husband died a few years ago and so I've got some time on my hands. It's quite nice to be able to take part in in things that are important like this.

I'm here today for my six-monthly visit to the Octopus trial to have all the different tests and so on that I need at 6 months, including another MRI and neuro tests and so on. But also, we're making a film and I'm going to ask some of the people who are leading this trial some questions in the hope that other people with MS might like to hear the answers to and make up their mind as to whether they might be interested in joining.

01:17

Jane: What will I need to do if I want to take part?

Jeremy: Okay so in the in the Octopus trial, you've looked at the portal and you've put your name into the portal hosted by the MS Society. So that takes all the basic details, and then confidentially all the names go out to the different trial sites around the United Kingdom. And then they'll give you a call and they'll go through again some fairly simple questions to make sure that the Octopus trial is right for you and if you're right for it, if you see what I mean. And then they'll plan with your diary a face to face visit and then they'll start the screening process. The first thing, of course, is the patient information leaflet that you'll be sent and then you'll read in advance. If you have any initial questions on that and then we can sent you for the trial.

Batoul: So basically once you fill out the online participant form you will have like an initial screening phone call with one of the doctors. And then we'll book you in for an initial visit. And if you are happy we will ask you to like sign a consent form during your first screening visit

Jane: Right, thank you

Jeremy: And that gets the ball rolling, as it were.

02:39

Jane: Yes, yeah great great. And how often do will I need to come to hospital?

Jeremy: Batoul,

Batoul: Yeah, so basically you will have the first screening visit, you will have an MRI and blood tests done and after reviewing these blood tests and MRI we will book you in for a randomisation visit, which is the first initial visit that you will get the medication during it. And afterwards you will start the medication, we will book you in for the first visit after four weeks, just to see how you are doing with the medication. And if everything is fine and we'll do some blood tests and if you are not having any side effects we will ask you to increase to full dose, for four tablets per day, and then you will book you in for a visit like after 12 weeks, and then you will need to come to the hospital or to the clinic every six months. And in between we'll have a phone call and we'll ask you to do a urine test.

Jeremy: Yeah, because we start with half dose for the first month and then we build up to the full dose after that

03:47

Jane: And how long can those six-monthly visits go on for?

Batoul: Up to five years

Jeremy: So how long does a typical six-monthly visit take do you?

Batoul: So let's start with the screening visit. We'll have uh booked for around one and a half hours and then one hour to go through your consenting process. The next visit which is the randomisation visit, it takes around 1 hour and a half. And we'll book you in for the initial visit four weeks after, it takes around 30 minutes. And the 12 weeks takes around as well 30 minutes. And your six-monthly visits will take around 2 and a half hours, including an MRI

04:30

Jane: Do I have to take part in Octopus?

Jeremy: No, it's entirely voluntary, it's entirely what you'd like to do. If it's not right for you, absolutely fine there's totally no compulsion. Everyone is always on the best standard of care so it will never compromise your best treatment. But as we said we hope to add in this, to see if we can produce new medications but it's entirely voluntary

04:54

Jane: And can I stop taking part after I joined the study already?

Jeremy: Yes, again again if you like, the rules of trials are that if you want to take part, want to stop taking part for any reason you can do that. You don't have to give any explanation to us. Of course, we hope that you won't, but it's entirely within your medical and your legal rights to do that.

Batoul: So if you decide to stop taking the trial medication, we will still invite you to attend hospital visits every six months so that we can keep collecting information about you for up to 5 years. And this is very important because we can make sure that the uh results of the study are reliable. And this will be discussed with the study or doctor or the nurse. But if you decide to withdraw from the study, you can carry on with your standard of care and this should be discussed with your neurologist.

05:55

Jane: That's good to know, yeah. Thank you. And why is there Placebo in the Octopus trial or sometimes called a dummy drug?

Jeremy: Yes, that's a good question. So the way we develop medicines is that we always have to compare them against something. So a new medicine must always be compared with an old medicine or if there's no old medicine with nothing if you like to make sure that it's better than nothing, better than an old medicine. This is important because all medicines have side effects or can have side effects and want to be utterly convinced that a new medicine is really working. Patients in this trial will be on the best standard of care. And then there'll be a flip of the coin if you like and then they'll be on the dummy treatment or treatment number one or treatment number two or new treatments as they come in.

06:41

Jane: When will I find out what treatment I've been on?

Jeremy: Yes, that's a really good question. It's a long trial and if a person happens to be on a treatment that doesn't work then we will tell people that they're on a treatment that doesn't work. And then 6 months later, in fact, if they so wish, they can come back into the trial and carry on with the Octopus trial. Now if a patient is on a person is on a treatment that does work all the all the dummy treatment they'll be carrying on for up to five years or so. But we certainly will plan at the end of the trial or at important points in the trial to let people know what they're on when it's when it's appropriate.

07:25

Jane: Yeah, thank you. Could I experience some side effects?

Batoul: Yeah, there is a list of side effects that you're going to we're going to discuss during your initial visit. We're going to go through all the side effects such as gastrointestinal, nausea, vomiting. Other than that, we will send some tests every time you come in for your visit and then we're going to check, we go through them if there is any abnormal results and we'll discuss this with you as well.

Jeremy: It's fair to say that most people don't have side effects, in fact, but we always want to make sure that a person is aware of all the possible side effects. We've done quite a lot of work on this, in terms of talking to people about possible side effects and generally I think our experiences that they tend to settle down if they are any over a few weeks. And also when the best time to have the medication is in relationship to meals. So, our experience here with nearly in this side 100 participants has really been invaluable in earning out all of that.

Batoul: So, basically on your randomisation day you will have a card that it says that you are taking part in this trial and then there is a list of the side effects that you might experience as a result of these treatments. And also there is like the contact details of the people that you should contact in case of any illness or any side effects.

Jane: Okay thank you. That's useful

Jeremy: There's always a contact numbers, full contacts are fully available during this trial, email, telephone, etc.

09:01

Jane: What about taking other medications?

Jeremy: So, people should always take the medications that they've been prescribed to by their doctor and we keep a list of those through the trial. Any change of medication that's very, very important to us. Of course, you shouldn't be on one of the treatment medications as well as coming into the trial where you could be double dosed, if you like, with one of the treatment medication. And we'll go through this in a lot of detail. But the essential message is that you can be on, you should be on all of your medications we always double check to make sure there's no interaction and if you're changing your medication then please let us know before you do change your medication

09:45

Jane: Okay, yeah. Are there any other precautions?

Jeremy: Well, in clinical trial we don't we don't, it's mandated that people should not become pregnant. So we have a very strict policy on that and we'll go through you with that in some detail.

Jane: And what if someone does become pregnant on the Octopus trial?

Jeremy: First thing to do is to call the trial Center and let us know, and you then you'll be instructed to stop the treatment medication. And then we have a full reporting system and follow-up system which will come into plac. I don't know but all if you'd like to..

Batoul: So basically there are some precautions that we will let the participant know during the first visit. So basically women of childbearing age must not become pregnant or breastfeed during this trial. There should be like appropriate method of contraception ideally two methods of contraception, and this should be discussed with the study doctor. If you have any question about if the method of contraception you are using is appropriate. And this should be at the start of the uh trial and up to 12 weeks after taking the trial medication. For men with a partner of childbearing who is pregnant or who could become pregnant, to use appropriate method of contraception during the study and after 12 weeks after finishing the trial medication. And a men should not donate sperm during this time like during the study period and after up to three months after the study ends.

11:24

Jane: So when should I stop taking the trial medication?

Batoul: So basically you will keep taking the trial medication as long as it's safe for you to take for up to five years. And at five years, if the medication you have been taking shows benefit, or it's still being assessed, you will have a conversation with your doctor about how this is going to happen. And if the treatment that you are taking does not show any benefits, you'll be asked to stop taking it and revert to your best standard of care. And like those modification will happen if there is any like major side effects, your study doctor will ask you to reduce or to stop the medication. And there is another option, if you would like to stop the trial medication, if you decide to stop. And the third option is that if this the medication you are taking shows no effect so we'll ask you after analysis, we'll ask you to stop taking the medication

12:23

Jane: Will I get back any travel costs?

Batoul: So basically on your initial visit we'll take you all your details and then you can claim all your travel expenses. But there is a limit that we can claim back

Jane: Thank you ever so much for answering all my questions. That's it's very useful information and very reassuring .

Jeremy: Thank you very much indeed. So ultimately this is all about people with multiple sclerosis, with Progressive multiple sclerosis, who've taken the time and the energy and the commitment to take part in the Octopus trial. And this has been a project which we developed over the last few years with the UK MS Society, which is funding this, to develop new treatments for Progressive multiple sclerosis. So, thank you for taking part in this really exciting project as we aim to push the boundaries of treatment in Progressive multiple sclerosis.