



FOCUS Trial Summary Pictorial Information Sheet

FOCUS: The efficacy of xanomeline-trospium in treating cognitive impairment in psychosis: A randomised double-blind active-controlled clinical trial

Why are we doing this trial?

People who have psychosis are usually given treatment to help them feel better. These drugs are called antipsychotics. They can be helpful for some patients, but less so for others. The patients who don't find them helpful often want to change to another treatment to help them feel better. Many people with psychosis have problems with things like concentration, memory, learning, and day to day activities. We call these 'cognitive' problems. We want to see if a new antipsychotic drug called 'xanomeline-trospium' (also known as Cobenfy) can help to treat these symptoms as well as the symptoms of psychosis.

Why xanomeline-trospium?

Xanomeline-trospium works in a different way in your brain to the usual antipsychotic treatments. Experts have done studies that show that xanomeline-trospium is as good as the usual drugs at treating psychosis. The study also showed that there were signs that show that xanomeline-trospium also treats the cognitive symptoms, so we are carrying out the FOCUS trial to see if xanomeline-trospium is better than the usual treatments at making people with psychosis feel better.

What does the trial involve?



We will include 150 people with psychosis aged between 18 and 55 years.



For 6 weeks, you will stop taking your usual treatment and start taking xanomeline-trospium or one of the usual treatments, called risperidone or lurasidone. The doctor will help you do this.



Which treatment you receive is chosen by a computer. Neither you nor the doctors will know which medication you are allocated to, and we cannot guess which treatment the computer has chosen. You will have a 50% chance of receiving xanomeline-trospium, and 50% chance of receiving risperidone or lurasidone.



We also want to understand how xanomeline-trospium works in the brain. For this, we would need to do two different types of brain scans. This will be discussed with you when you see the doctor. While we will be asking all participants to take part in the brain scans, you do not have to do this to take part in the trial. The brain scans don't involve any dangerous radiation.

What to expect?



You will be asked to attend 4 visits, which will take between 2 and 4 hours each time you come in. Each visit will be slightly different. Some visits may be longer than others.



You will be given £20 per visit, and then another £50 if you attend all 4 visits
You will be given £50 per brain scan.



A doctor will examine your health by weighing and measuring you, and checking your heart. There will be a blood test, and a urine pregnancy test if you are of child-bearing potential.



We will ask you questions about your health, what medicines you are taking, and about some experiences in your past.



We will ask you to complete two easy tests on an iPad, which will be a bit like a computer game.

What happens at the end of the trial?



After the end of the 6 weeks where you take the new trial medication, you will be told whether you received xanomeline-trospium or a usual psychosis treatment. If you received xanomeline-trospium and you want to keep taking this medication, you can do this for another year, as long as you are able to see us for one more appointment at the end of that year. If you were taking a standard antipsychotic, your participation in the trial will end after six weeks, and decisions about your treatment will be handed back to your usual clinical team or psychiatrist.

Do you need more information?

For more information, please email FOCUS@psych.ox.ac.uk or phone <insert telephone number>.