

Video transcript: ATLANTIS Introduction for participants, Professor Alexander Ford

ATLANTIS is a medical research study designed to find out whether a drug called amitriptyline can help people with irritable bowel syndrome (IBS).

IBS is a common condition and it causes symptoms like on-going tummy pain, bloating and changes in bowel habits. IBS is usually a lifelong problem, with no cure and it being difficult to treat, it can be very frustrating to live with and can have a big impact on everyday life.

Amitriptyline is a drug that can be used to treat IBS. Amitriptyline is a drug which has been used safely for more than 50 years and is an antidepressant. However, like most drugs it has other effects. In ATLANTIS we are mainly interested in its effects on pain and bowel habits. When it is used as an antidepressant, it is given in much higher doses than the small doses we are using in ATLANTIS. Some studies have shown that using amitriptyline at a low dose relieves pain and changes bowel habit in people with IBS. However, these studies have been small and have only looked at people with IBS seeing specialist doctors in hospital clinics. In ATLANTIS, we want to find out whether using amitriptyline in patients who have seen their GP with IBS and in whom first-line treatments such as changes to diet, antispasmodic drugs, laxatives and anti-diarrheal medications have not worked, will lead to an improvement in bowel symptoms and quality of life.

The results from this study are important, as they will help doctors decide whether they should be using small doses of amitriptyline routinely as a treatment for IBS.

In order to find out if amitriptyline works, we need to do a large clinical trial to examine it very carefully. To do this, we plan to recruit over 500 people, all of whom have previously seen their GP and have tried first-line treatments for IBS, with no benefit. People will be identified from GP practices across regions in Bristol, Southampton and West Yorkshire.

A computer will choose half the participants to receive amitriptyline and the other half to receive a dummy treatment called a placebo, at random. We are using a placebo tablet as this is a good way to test if a drug really works. It is well known that some people find their symptoms get better (at least in the short term) when they are given a dummy medicine, and we need to know whether amitriptyline is better than this. Neither the participant, nor the research staff in the study clinic, nor those of us running the study centrally will know who is on amitriptyline and who is on placebo. All of this is really important to help us to ensure we give the drug a completely fair test and therefore get a clear and reliable answer. The results of this trial is important as it could affect medical treatment for millions of people with IBS around the world. People taking part will be able to find out at the end of the study whether they have been given amitriptyline or placebo.

The study will carry on for at least a year. If you choose to take part, you will be asked to take the study drug for 6 months initially and then decide whether you want to carry on for a further 6 months, or stop taking the drug. You will have a 50:50 chance of receiving amitriptyline or the placebo tablet. You are free to withdraw from the study at any time without giving a reason.

If you have been invited to take part in this study then you may have received a leaflet containing more information. Please read this carefully before you decide whether to take part and do feel free to contact the research team if you have any questions.

Thank you for your interest in this important medical research study.