



TRIAL SUMMARY

Trial Name:

**Antidepressant Trial with P2X7 Antagonist JNJ-54175446
(ATP)**



We would like to invite you to join this antidepressant trial. If you are currently suffering from symptoms of depression and are taking antidepressants, this trial may be of interest to you.

Purpose of the trial

- Many patients with depression have symptoms that remain despite treatment with antidepressant medications.
- Scientific evidence has shown a link between inflammation and depression.
- This trial aims to test whether a new anti-inflammatory drug JNJ-54175446 when taken together with your current antidepressant medication can help to treat your depression.
- We aim to recruit 142 participants currently suffering from depression to this trial.

What does this trial involve?

- If you are interested in taking part, you will be asked some general questions over the telephone to check your suitability.
- If you meet our pre-screening criteria, you will be invited to attend a screening visit at the clinic. This would take about 4 hours. At this visit we will carry out a range of assessments to determine your eligibility. As there are strict criteria to take part in this trial, there is a reasonable chance that you might not be eligible.
- If you are eligible to take part you will be required to make 4 more visits to the research centre over approximately 10 weeks. The visits will take between 1.5 hours to 5 hours. You will have to fast overnight (10hrs) for 2 visits.
- You will be randomly allocated to either the active drug group or the placebo (dummy drug) group. You will then take the allocated drug daily for about 8 weeks, alongside your current antidepressant medication. You will not know which group you have been allocated to.
- At the visits you will be asked questions about your depression and mental health, and perform some tasks on a computer.
- You will provide blood and urine samples for various tests, and undergo ECG¹ and MRI² scans.
- You will also complete some activities at home that include providing saliva samples and wearing a wrist activity monitoring device.

¹ Electrocardiogram (ECG): recording of the electrical activity of your heart

² Magnetic Resonance Imaging (MRI): non-invasive procedure that uses radio-frequency and magnetic fields to produce images of your brain and body



Potential benefits of taking part

- You may experience some improvements in your symptoms of depression.
- You will be compensated for reasonable travel expenses.
- You will receive up to £500 for your time and effort in the trial. The exact amount will depend on the number of visits you have completed.

Potential disadvantages of taking part

- The drug has been tested on more than 300 people already and has been shown to be very safe. Mild side-effects that were seen include headache, fatigue and nausea
- You will not receive any more trial drug after the trial, even if your symptoms improved during the trial

Will I be eligible to take part?

As this is a drug trial, there are strict criteria that need to be fulfilled before you can be enrolled. We have listed some of the key criteria below:

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| <ul style="list-style-type: none">✓ Aged between 18 and 60 years inclusive✓ Body mass index (BMI) of 18.0 to 36.0✓ Currently being treated with an antidepressant medication✓ Currently experiencing symptoms of major depression✓ Willing to undergo MRI scans |
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We are not able to enrol you to the trial if you have any of the following:

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| <ul style="list-style-type: none">X Currently diagnosed with a psychotic disorder such as schizophrenia, bipolar disorder or an eating disorderX Have had any metal implants/fragments in the bodyX Pregnant, planning to be pregnant or breast-feedingX Regularly using recreational drugsX Regular high intake of alcoholic beverages |
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Do I have to take part?

Participating in this trial is completely voluntary. If you decide to participate you will be asked to sign an Informed Consent Form, however you are still free to change your mind and leave the trial at any time without giving a reason. If you choose not to participate or to leave the trial, your future medical treatment and normal standard of care will not be affected in any way.

Who is organising (sponsoring) and funding the trial?

This trial is taking place across a number of centres in the UK. The trial is primarily funded by the Wellcome Trust. Janssen Pharmaceuticals is partially funding the trial and will also be providing the trial drug free of charge, and is sponsored by Cambridgeshire and Peterborough NHS Foundation Trust and the University of Cambridge.

For further information about the trial, please contact your local research team.

Many thanks for your time and interest.