NIHR | Oxford Health Biomedical Research Centre

PAX-D Research Trial: Patient Advisory Group

Introduction

PAX-D is a randomised placebo-controlled trial, that will evaluate the drug pramipexole as add-on treatment for people with treatment resistant depression (TRD). Further details can be found in Appendix A: Trial Summary.

The Chief Investigator is Professor John Geddes, NIHR Oxford Health Biomedical Research Centre.

We are setting up a Patient Advisory Group (PAG) for the trial, to provide insight from those with lived experience of treatment resistant depression.

About the Patient Advisory Group

The Patient Advisory Group (PAG) will be comprised of patients and carers, and its membership will be between 4 – 6 people.

The group will help ensure the research is both relevant and feasible, and members will be involved in:

- Finalising trial design making sure what we are asking participants to do is reasonable
- Ensuring recruitment and participant information is presented in a way that is understandable
- Discussing the interpretation of the data
- Planning the dissemination of results

We envisage the group will last for the duration of trial, from June 2019 until December 2023. We anticipate the group activities will be as below, but this will be discussed and finalised with group members:

- Study set up & pilot phase: two meetings of up to 2.5 hours, plus reviewing documents from home
- During the trial: three annual meetings up to 2.5 hours
- End of the trial: one meeting up to 2.5 hours
- Other occasional remote feedback

Members of PAG will have expenses paid plus be offered reimbursement for their time, as outlined in Oxford Health Biomedical Research Centre's payment policy.

The PAG will be coordinated by a member of the study team. Members of the PAG will be supported through the provision of background and introductory information, a named contact, and 6-monthly progress updates (by email) during the study.

Dates and times for any meetings will be agreed between PAG members and the research team. Meetings will take place in Oxford.

Criteria for Patient Advisory Group members

We ask that all PAG members:

- Have experience of treatment resistant depression either as a patient or a carer
- Have an interest in medical research
- Are willing to share your experience as a patient or carer, and your reflections on how someone with similar experience may respond to various aspects of the study design
- Have a willingness to listen to, and consider, different perspectives and opinions
- Are based within a reasonable travel distance of Oxford

Expressions of interest and contact details

If you would be interested in nominating yourself to join the Patient Advisory Group please get in touch with us on the email address below **indicating how you meet the criteria in the section above**.

We encourage interested people to get in touch with us as soon as possible. The deadline for expressions of interest is 13 June 2019, but if we receive a large number of contacts we may fill all the spaces in the group before this date.

Please also get in touch if you have any questions or would like further details.

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Appendix A: PAX-D Trial Summary

Clinical depression is a common disorder usually treated in primary care with psychological therapies and antidepressant medication. However a significant proportion of people (about 2-3 in 10) do not improve with current first-line therapies and are regarded as having treatment resistant depression (TRD).

TRD is a major problem for both patients and society because of the high level of suffering and associated disability. Current medicines for TRD are not particularly effective for many people and often have adverse effects which patients find distressing.

There is some evidence that pramipexole, a medicine already commonly used in Parkinson's Disease, may be an effective treatment for TRD. PAX-D will compare the effects of pramipexole with placebo when added to current antidepressant medication for people with TRD. The trial will look at effectiveness in the short- term (after 12 week's treatment) and in the longer-term (48 weeks). The trial will also assess the adverse effects of pramipexole and explore patients' experiences of taking it.

Pramipexole is unlike current antidepressant drugs in that it acts like a brain chemical called dopamine, which is known to influence people's motivation to pursue goals and affect how rewarding they find them. Lack of motivation is a key symptom of depression so any antidepressant effects of pramipexole may be linked to increased motivation. PAX-D participants will be asked to carry out a computer task designed to measure how pramipexole affects the dopamine system in the brain and how far this can explain its antidepressant effects.

If pramipexole is effective it could become a very useful treatment option for patients with TRD and this information will be disseminated through scientific publications, meetings with patient groups and NHS innovation programmes.