

# BALANCE

Bipolar Affective disorder: Lithium/ANti-Convulsant Evaluation

## Trial of lithium & valproate in bipolar disorder

### Bipolar disorder

Most people experience mild mood changes between happiness and sadness. These are often caused by the things that happen to them in everyday life. For some, however, these mood changes can be severe enough to interfere with day-to-day functioning. These people suffer from bipolar disorder (also known as manic depression). Sustained elevated or irritable mood is called a manic episode and sustained low mood, loss of energy and sadness is called a depressive episode. About 1 person in 100 suffers from bipolar disorder which affects their lives and the lives of those who live and work with them. Many will face the disruption of repeated admissions to hospital.

### The need for a trial

Many people who have had recurrent episodes of bipolar disorder need regular long-term medicine to prevent manic and depressive relapses and to provide improved day-to-day stability of mood. Several medicines are available but it is unclear which is the most effective, or if they work best on their own or in combination. The best way to compare treatments for any illness is to conduct a clinical trial but, to date, very little research has been done comparing treatments for prevention of manic and depressive episodes in bipolar disorder.

### The BALANCE Trial

**BALANCE** is a large scale randomised clinical trial comparing the effectiveness of three frequently used treatments for relapse prevention:-

- lithium alone
- valproate semisodium alone
- lithium and valproate semisodium combination

**BALANCE** has been designed to produce helpful and reliable results – and to cause as little inconvenience as possible to participants and their doctors.

### Participants

People are eligible to participate in the trial if they:

- agree to take part
- have had an episode of mania
- are likely to benefit from treatment
- are unsure which treatment is best

### Run-in phase

Everyone who joins the trial will be given both lithium and valproate semisodium for up to 8 weeks. This “run-in phase” will ensure that participants are able to tolerate both drugs.

At the end of the run-in phase participants will enter the randomised phase of the trial and be allocated to one of the three treatments for up to two years.

### Randomised phase

During this time information about the effectiveness of treatments will be collected. Apart from one additional blood test after randomisation, the trial does not involve extra tests or clinic appointments.

Participants will be sent a brief questionnaire annually and psychiatrists will be asked to complete a follow-up form 3 or 6 monthly.

## Completion of the trial

At the end of the trial, participants will discuss with their psychiatrist whether to continue with the treatment that they took during the trial or to change to a different treatment.

## Effective treatment

An effective long-term treatment is one which reduces the risk of manic or depressive episodes without unpleasant side-effects or long-term lowering of mood.

In the **BALANCE** Trial, the main measures of effectiveness are:

- reduction in number of people admitted to hospital
- reduction in use of additional medication for mood symptoms

The trial will also measure:

- side-effects
- long-term effects on mood
- quality of life
- deliberate self harm

## Support for BALANCE

The trial is being funded by a US mental health charity, the Stanley Medical Research Institute

The University of Oxford is the sponsor of the trial.

Priadel and Depakote have been donated by Sanofi-Aventis. The trial has been designed independently of the manufacturers of the drugs.

The trial has the support of the Mental Health Research Network.

## FAQs

### Will participants get the best treatment?

People should only take part in the trial if both they and their psychiatrist are uncertain about which of the trial treatments would be best for them. This uncertainty means that random allocation of treatment is just as likely to select the best treatment for them as any other way of selecting treatment.

### Will all participants receive active treatment?

Yes, everyone will receive lithium and/or valproate semisodium. No-one will be given a placebo.

### Who will know which drugs are allocated?

**BALANCE** is an open-treatment trial in which both participants and their doctors will know exactly which drugs have been allocated.

### Will General Practitioners be informed?

GPs will be kept informed about the trial by psychiatrists and by the **BALANCE** Office.

### What happens if the treatment is not effective?

If it is clear that trial treatment is not effective it can be stopped and new treatment started. If this happens during the randomised phase, the participant can continue to take part in the trial.

### Can participants withdraw from the trial?

Participants can withdraw from the trial at any time and return to normal medical care.

## Contact details

For more information:

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