

BANDIT CLINICAL TRIAL

(baricitinib in new onset type 1 diabetes)

Information Sheet

Have you, or someone you know, recently been diagnosed with type 1 diabetes?

We are looking for volunteers aged 10 – 30, who have been diagnosed with type 1 diabetes within the last 100 days, to participate in the BANDIT trial. The trial will determine if the drug baricitinib, currently available for rheumatoid arthritis sufferers, reduces the loss of insulin-producing cells in the pancreas. There are currently no treatments available that can do this, and this is the first time baricitinib is being tested in people with type 1 diabetes.

Who can participate?

People aged 10 – 30, who have been diagnosed with type 1 diabetes within the last 100 days, may be eligible to participate.

Where is the trial being conducted and how long will it last?

This is an Australian-based trial being undertaken over 2 years at three sites in Melbourne Australia: The Royal Melbourne Hospital, The Royal Children's Hospital Melbourne and St Vincent's Hospital Melbourne and at one study site in Adelaide, the Women's and Children's Hospital.

Why should I participate in this trial?

If the drug helps to preserve a participant's ability to make insulin, they may find it easier to control glucose levels and may be able to decrease their insulin doses. Participants will help to advance type 1 diabetes research and may also benefit from the additional monitoring of their diabetes provided by the trial and from close interaction with the research team.

What kind of things will the trial participant have to do?

Participants will be asked to provide details of their medical history and be examined by a trial doctor.

Blood samples will be collected to check for blood cell counts, liver and kidney function, blood glucose levels and other measurements such as immune system genes, called HLA, which play an important role in the development of type 1 diabetes.

During the trial, participants will be asked to undertake meal tests, and have a glucose monitor fitted at times.

In between the trial visits at the hospital, a member of the trial team will contact them regularly by telephone to enquire about any concerns and to review their insulin treatment.

Is there a cost to participate in the BANDIT trial?

No; all medication, tests and medical care required as part of the research project will be provided free of charge. Participants will be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit.

How will the trial work?

There will be two groups in this trial – two thirds of the participants will need to take a baricitinib tablet once per day and one third of the participants will take a placebo tablet once per day.

A placebo looks like the real drug but has no active ingredients. The main reason to have a placebo group is to be sure that any effects are caused by the treatment and not by something else.

How will participant privacy be managed?

All identifying information will be kept confidential. When the results of this trial are known, they will be made available to participants who ask for them.

Who is leading the BANDIT trial?

The BANDIT trial is being led by St Vincent's Institute of Medical Research (SVI) in Melbourne Australia, with funding provided by the Juvenile Diabetes Research Foundation (JDRF).

Who has approved the research project?

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of the Royal Melbourne Hospital (Melbourne Health). It will be carried out according to the Australian Government's National Statement on Ethical Conduct in Human Research (2007). The trial is registered with the Australian New Zealand Clinical Trial Registry: ACTRN12620000239965.

Where can I get more information about the trial?

- Please contact the BANDIT Trial Coordinator via email at bandit@svi.edu.au or phone on **0450 323 962** or
- Associate Professor John Wentworth via email at john.wentworth@mh.org.au or phone on **(03) 9342 7344**.

Alternatively, you can fill out an enquiry form on the website www.svi.edu.au/bandit