

TITLE

A study of an experimental new medicine in people with coeliac disease

Introduction

Hammersmith Medicines Research (HMR), in North West London, is carrying out a study to test an experimental new medicine in people with coeliac disease. The study medicine isn't going to be a cure for coeliac disease, but it might prevent symptoms when someone with the condition eats gluten by accident.

Who can take part?

If you would like to take part in the study you must:

- have previously had a biopsy (a small sample) from the lining of your gut that confirmed you have coeliac disease
- be otherwise healthy, and aged 18–60
- have been on a gluten-free diet for at least 1 year
- not have very severe reactions when you eat gluten
- not be allergic to or intolerant of any other food

What is involved?

If you take part, you'd take 2 doses of the study medicine every day, for 28 days, and you'd have 3 overnight stays and 4 outpatient visits at HMR in North West London. So far, single and repeated doses of the study medicine have been tested in healthy people. There were no important side effects.

You'd follow your usual gluten-free diet during the study, but every day for 13 days in a row, you'd also need to eat about 3 slices of bread made from wheat, which contains gluten. Participants would need to eat the bread, so the study team can test whether the body has a reaction to the gluten.

The study team will monitor volunteers closely. Some people who take part in the study might have symptoms caused by the study medicine, eating gluten, or something else. If you take part and you wanted to talk to someone about any symptoms you might have, a doctor is available at HMR at all times during the study, day and night and at weekends.

How to take part

If you are interested in taking part in the study, or would like more information, please contact HMR by:

**Phoning HMR on:
0800 783 87 92 or on 020 8963 4502**

**Emailing HMR at:
recruit@hmrlondon.com**

You can also find out more about HMR by visiting www.londontrials.com. Please note that by making contact and showing an interest, you are not obliged to take part in the study.

If you decide to take part and complete the study, you'd be paid up to £1,800 for your time and inconvenience.

The study is being organised by HMR and has been approved by East of England - Cambridgeshire and Hertfordshire Ethics Committee. The study is funded by F. Hoffmann-La Roche.