



GlaxoSmithKline

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Brief Information Sheet

Gene variants influence on GSK1521498 effects on food & alcohol cues

Study OAA116753

This document gives brief information about a study conducted in the GlaxoSmithKline Clinical Unit in Cambridge (CUC), based in Addenbrooke's Hospital.

The GSK study drug, GSK1521498, blocks the effects of messenger molecules in the brain called opioids, which are chemicals in the body that are involved in how the body responds to rewards, including diet and alcoholic beverages. GSK1521498 may therefore have use for some forms of addiction. This clinical research study is designed to compare the effects of GSK1521498, of another drug (naltrexone) which is licensed as a treatment for some forms of addiction, and against a dummy drug (placebo). There is evidence that variation in a specific gene can influence the response to this type of drug, and this will be investigated in this study.

The study is randomised and double-blind. This means that you will receive the 3 treatments on 3 separate treatment periods during the study (GSK1521498, naltrexone, dummy drug), but you and the study team do not know the order in which you receive the treatments, and what you are receiving. The CUC study team does not know which gene type you have.

The diagram on the next page tells you what will be happening during the study. There will be 1 screening visit, 3 treatment periods (separated by at least 2 weeks without treatment), and 1 follow-up visit. In total, the duration of the study is approximately 12 to 13 weeks. You will be compensated for travel expenses and time involved in the study.

Study procedures include a variety of mood questionnaires, an MRI brain scan, computer tests to measure reaction time, and blood samples (all of these investigations have been used many times in clinical practice and are not harmful). The MRI brain scan will be performed at the Wolfson Brain Imaging Centre (WBIC) at Addenbrooke's Hospital.

You will be asked to maintain some restrictions throughout the study, for example some restrictions on alcoholic beverages, diet and driving - for some of the time during the study. These will be discussed with you in detail if you wish to participate in the study.

Study diagram:

