



Clinical and Surgical Sciences (Anaesthesia, Critical Care and Pain Medicine)
SCHOOL of CLINICAL SCIENCES and COMMUNITY HEALTH

The University of Edinburgh
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Effects of Alcohol in the Laboratory and in Everyday Life

You are being invited to take part in a research study being carried out by Edinburgh University at the Royal Infirmary of Edinburgh. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

A total of 30 volunteers will be involved. Volunteers should be aged 18-65, drink alcohol but not to excess, and be in good general health. There will be a general health check-up before the study. Women who are pregnant or likely to become pregnant during the study should not take part. Female volunteers will be asked to take a pregnancy test (unless post-menopausal or otherwise unable to become pregnant). Your GP will be informed that you are taking part. If you do not currently have a GP, registration with a GP will be necessary before you can take part. If you have any medical condition, are currently taking medication of any sort, are allergic or sensitive to any drug, or if you have recently participated in any other drug study, you should tell the investigator.

What is the purpose of the study?

Alcohol (ethanol) is known to cause impairment to skilled performance and to increase the risk of accidents. A great deal of work has been carried out in the laboratory, but rather little research has been done on performance testing in an everyday life setting.

This study will involve carrying out performance tests set up on a mobile phone over a two-week period, followed by a laboratory-based study. This will allow us to compare results between the two settings, and also to evaluate the use of this new technology in drug research.

What will happen to me if I take part in the study?

There will be an initial medical screening visit, as described above, at which your written consent will be recorded. You will then be asked to attend a training/practise session lasting about 1 hour. Screening and practice sessions will take place in the University (George Square). You will be shown the use of the phone tests, which may be installed either on your own phone or on a phone we supply to you, and will practise



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them. You will then be asked to carry the phone around with you for two weeks, and to complete the tests twice a day, each time being as soon as possible after you receive a text message asking you to do so. During this period we ask you not to change your behaviour in any way as a result of being in the study.

You will then be asked to attend the Royal Infirmary of Edinburgh on two occasions on separate days. In each session you will receive a drink that may or may not contain ethanol, and carry out the tests before and after the drink, as well as completing a questionnaire.. Each session will last about 2.5h, after which you will return home by taxi.

You should not drink any alcohol from 24h before each session until 24h after taking the drink. There will also be restrictions on caffeine (tea, coffee, cola-type drinks) and tobacco on test days until all tests are completed. You should not drive or cycle or make important decisions after the main test sessions for the rest of the day.

Will there be any payment?

You will be paid £65 if you complete the study. In addition you will be paid for your taxi fares home from the Infirmary on the two lab sessions.

Do I have to take part?

Participation in the study is completely voluntary. You are free to withdraw from the study at any time without stating a reason. If you withdraw after taking a study drink, however, you must continue to follow the instructions concerning driving and other activities described above.

Will my taking part in this study be kept confidential?

The study will be carried out by a team from the University of Edinburgh at the Edinburgh Royal Infirmary. Data from the study will be stored and analysed by computer, and the provisions of the Data Protection Act 1984 will be applicable. No data from which you can be identified will be made available to anyone other than the research team and your G.P. unless you give your written consent.



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What if something goes wrong?

Your participation in this study comes under the terms of the University of Edinburgh's insurance arrangements which cover the University's legal liabilities if harm should arise.

Who has reviewed this study?

The study has been reviewed by the Lothian Local Research Ethics Committee.

Where can I obtain further information about the study?

You will be given a copy of this information sheet to keep. If you have any questions about the study, please do not hesitate to ask one of the investigators, or Dr D McKeown, Department of Anaesthesia, Critical Care and Pain Medicine, Royal Infirmary of Edinburgh

Thank you for taking time to read this information sheet



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INSTRUCTIONS:

- FOOD INTAKE -** Please do not eat anything in the four hours before taking part in the study, and have only a light meal before this time. This is important, as food slows down the absorption of ethanol.
- CAFFEINE -** You should have a maximum of one cup of tea or coffee on the mornings preceding test sessions, and this should be the same on each day. No further caffeine should be consumed on the day of the test session until completion of all procedures. Note that many soft drinks contain caffeine, and these should not be consumed.
- SMOKING -** You should refrain from smoking on study days from two hours before the session starts until after you have completed the final test on the study day.
- ALCOHOL -** You must refrain from alcohol during the 24h preceding the test session and until 24h after you took the study drink.
- MEDICATION -** No other medication must be taken on test days unless agreed in advance by the investigator. You must inform the investigators if you have taken any medication of any kind since the previous visit.
- DRIVING -** You must not drive or cycle after the test session, for the rest of the day.
- WORK -** No important work commitments should be undertaken or important decisions made after the test session for the rest of the day. Nor should you use potentially dangerous equipment (such as power drills, saws etc.), for the rest of the day.
- ADVERSE EVENTS -** If you feel unwell, inform the investigator immediately.