You have been invited to take part in a laboratory practical class. Before you decide whether to take part it is important for you to understand why the practical is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and the lead academic if you wish to. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. If you decide to take part you may keep this leaflet. Thank you for reading this.

**Background**

The aim of this study is to investigate the influence of route of administration and formulation on the pharmacological actions of atropine, this to consolidate and exemplify information presented to you in B32C03.

**What does the study involve?**

The study will involve a single five-hour laboratory session, in which atropine (or placebo) will be administered, and pulse rate, salivary flow, and pupil diameter or accommodation measured at various time-points. This will be set up as a double-blind, placebo-controlled trial; descriptions of these terms are given below:

*Blind Trial:* In a blind trial you will not know which treatment group you are in. If the trial is a double blind trial, neither you nor your observer will know in which treatment group you are.

*Placebo:* A placebo is a dummy treatment such as an injection, oral solution or capsule which looks like the real thing but is not. It contains no active ingredient.

**Do you have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

**What do I have to do?**

If you are on a medication or have an illness, you should consult with the clinician who provides medical cover to this class, who will decide if you are suitable to act as a volunteer.

There are no dietary restrictions before or during the class.

**What is the drug or procedure that is being tested?**

Atropine is a well-established muscarinic antagonist that is used in a wide variety of clinical situations.

Atropine (or placebo) will be administered by either sub-cutaneous injection (dose of 12µg/kg) or oral route (solution or capsule; dose of 1.2mg).
What are the side-effects of any treatment or procedures received when taking part? What are the possible disadvantages and risks of taking part?

No side-effects of the atropine treatment are expected – this class has run for over 20 years (sub-cutaneous administration) with no adverse events recorded.

The doses of atropine used are designed to produce only small and short-lived pharmacological responses.

The injection may produce transient pain and a bruise at the site of injection, but this should be no different from immunisation injections you received at school.

You may not be a subject for this class if you are pregnant, breast-feeding, or suffer from any disease of the eyes, gastro-intestinal system, or cardiovascular system.

What if something goes wrong? Who can I complain to?

In case you have a complaint on your treatment by a member of staff or anything to do with the study, you can initially approach the lead staff member. If this achieves no satisfactory outcome, you should then contact the Ethics Committee Secretary, Mrs Louise Sabir, Division of Therapeutics and Molecular Medicine, D Floor, South Block, Queen’s Medical Centre, Nottingham, NG7 2UH. Telephone 0115 8231063. E-mail louise.sabir@nottingham.ac.uk.

In the unlikely event that you suffer injury to yourself or damage to your property as a result in taking part in this class, the University does have an insurance policy to cover harm arising as a result of the defect in the design of the study. In addition, all medical practitioners taking part in the class have personal medical negligence cover.

Will my taking part in this study be kept confidential?

The master data-sheets generated in the class will be kept by the lead staff member for archive purposes, and any information about you which leaves the School of Biomedical Sciences will be anonymised so that you cannot be recognised from it.

What will happen to the results of the study?

The results of this study are principally intended for use in a laboratory write-up.

Who is organising and funding the study?

The School of Biomedical Sciences is organising and funding this class.

Who has reviewed the study?

This study has been reviewed and approved by the University of Nottingham Medical School Ethics Committee.

Contact for Further Information

Contact: Dr Jeffrey Fry (tel: 0115 8230160; email: jeff.fry@nottingham.ac.uk)

Thank you for showing interest in becoming a volunteer for this study.