TELL US WHAT

 DO YOU THINK

Y o u r o p i n i o n m a t t e r s



* **This study is about the acceptability of the local anaesthetic (Wand or traditional) for young dental patients (the study is part of a student project and contribute towards a postgraduate academic qualification).**
* *We are inviting you to take part in a research study. Before you decide whether to participate or not 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 to decide whether or not you wish to be involved.*
* **1. What is the purpose of this study?**
* Some dental treatments can be painful and to avoid pain, dentists require to give local anaesthetic to their patients. The most common way of giving the local anaesthetic is with the traditional injection (dental syringe), however, some patients find it painful.
* Other tools have been introduced to give local anaesthetic and one of them is the Wand (a device used to inject the anaesthetic that is controlled by a computer). Dentists have been using this method for more than 20 years with their child-patients.

We are looking at your opinion about having local anaesthetic for dental treatment using either the normal injection or the Wand We would like you to rate your experience when you come next time to see your dentist and have dental treatment with local anaesthetic. We hope that the findings will help us answer this question and provide you with the service that best suits you.

* My name is Rema Elhaj-Husian and I am a PhD researcher and one of the research team.
* **2. Why have you been chosen?**
* You have been chosen because you are 10-16 years of age and requires dental treatment under local anaesthetic.
* **3. Do you have to take part?**
* It is up to you to decide whether or not to take part and if you did not wish to participate you will not be included in the study. You are free to withdraw at any time and without giving a reason and this would not have any consequences on your care or treatment.
* **4. What will happen if you take part?**
* Sometimes we don’t know which way of treating patients is best. To find out, we need to make comparisons between different treatments and ask you and others like you about what you thought of the treatment you’ve received. To do this, you and other young people will be randomly given one of the following local anaesthetic options by drawing a sealed envelope of the type of the anaesthetic device:
* 1. Traditional injection (dental syringe)
* 2. The Wand computer-controlled local anaesthetic system
* Your dentist normaly gives both of these ways and you will be having either of them even you do not take part in this study. Whichever one you will be given; it will be in the usual way by your dentist. Then the acceptability of bot techniques will be compared. This is called a randomised study.
* **5. What do you have to do if you participate?**
* It will all happen in one day and if you agree to take part, we will first ask you to sign a consent form after we read it together and answer any questions you may have. If you are unable to give consent, you will be withdrawn from the study. Then you will be given two sheets of questions that you need to answer, these are called questionnaires. They are about what you think of the dental anaesthesia (numbing teeth) and how much comfortable you are with having dental treatment. Then you will have your dental treatment with your dentist who will give you a scale to rate your experience of the dental anaesthetic you’ve had just after having it. After you finish your treatment with your dentist, you will be given the same questionnaires again with an extra one to answer and share your opinion with us. There are no right or wrong answers, and no one will know what you said as your name will not be written. There are no follow up visits required for this study apart from your routine treatment.
* **6. What are the possible benefits of taking part?**
* The information we will get from this study with your help and others will help understand young people’s opinion of different local anaesthetic delivery methods and what makes them acceptable. This will help improving the care you get.
* **7. What are the possible risks of taking part?**
* It will take extra time out of your day to complete the questionnaires (10-15 minutes). Otherwise, there are no known risks for participating in this study apart from the
* known risks of the local anaesthetic that will be explained by your dentist during the appointment.

**8. Will anyone else know you are doing the research?**
The people in our research team will know you are taking part. Nobody else will know. We’ll give you a number for the study instead of using your name so no one will know about what did you answer. All forms and questionnaires will be kept safe in a locked filing cabinet and a password protected computer database.

**9. What if you change your mind about taking part?**

If you decide to withdraw from the study, you can do so at any time – just let us know, your care will not be affected. We will keep information that we already had from you and stop collecting any more. You will still be asked to attend the usual follow-up clinics if required by your dentist at the hospital. These will not be part of the study.

**10. What if there is a problem?**

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated by members of staff due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask the researchers if you would like more information on this. In the unlikely event that you are harmed by taking part in this study, compensation may be available. If you suspect that the harm is the result of the Sponsor’s (University College London) or the hospital's negligence, then you may be able to claim compensation.  After discussing with researcher, please make the claim in writing to Prof. Paul Ashley who is the Chief Investigator (responsible) for the research and is based at: Unit of Craniofacial Growth and Development, UCL Eastman Dental Institute, 256 Gray's Inn Rd London, WC1X 8LD.

The Chief Investigator will then pass the claim to the Sponsor’s Insurers, via the Sponsor’s office. You may have to consider the costs of the legal action first, and you should consult a lawyer about this.

You may also need the UCLH Patient Advice & Liaison Service (PALS) address:

               PALS

               Ground Floor Atrium

               University College Hospital

               235 Euston Road

               London NW1 2BU

               Telephone: Main Hospital: 02034473042

               Email: uclh.pals@nhs.net

If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer. The research team can give you details of the right Data Protection Officer. If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner’s Office (ICO) ([www.ico.org.uk](https://ico.org.uk/)  or 0303 123 1113).

**11. How will we use information about you?**

We will need to use information from you and from your medical records for this research project. This information will include:

* NHS number
* Name
* Contact details

Only consent form will contain your name and hospital sticker. A digital copy will be made from the original consent form and will be stored securely (encrypted) and kept as long as the research data be retained (10 years), the original hard copy will then be destroyed securely by shredding. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. You can find out more about how we use your information

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* by asking one of the research team

**12. How will we use information you provide?**

We plan to publish the results in health journals and present them in health conferences so others can read about and learn from the results of the study. The study is also going to be published as part of the PhD thesis. If you require a copy of the results, you can contact the research team:

Research supervisors Prof. Paul Ashley (p.ashley@ucl.ac.uk) and Dr. Susan Parekh (s.parekh@ucl.ac.uk) or me the research student Mrs Rema Elhaj-Husian (rema.elhaj-husian.14@ucl.ac.uk). Unit of Craniofacial Growth and Development, UCL Eastman Dental Institute, 256 Gray's Inn Rd London, WC1X 8LD.

**13. What happens to your research data after the study?**

Researchers will make sure they write the reports about the study in a way that no-one can work out that you took part in the study.

Once they have finished they study, the research team will keep the research data for about 10 years, in case they need to check it. You can ask about who keep it, whether it includes your name and how long they will keep it.

Usually your hospital, where you are taking part in the study, will keep a copy of the research data along with your name for less than 3 months. The organisation running the research will usually only keep a coded copy of your research data without your name for about 10 years. This is kept so the results can be checked.

If you agree to take part in the research study, you will get the choice to give your research data from this study for future research. This future research will use research data after removing your name and NHS number and other researchers won’t be able to contact you to ask you about future research. Your data will not be used to sell you anything. It will not be given to other organisations or companies except for research.

**14. Who is organising and funding the research?**

The study is a PhD project organised by the unit of Craniofacial Growth & Development at the Eastman Dental Institute - University college of London, UK. Funding has been provided by the Cultural Affairs Office at the Libyan Embassy in London as I, Mrs Rema Elhaj-Husian, am a sponsored PhD student by the Ministry of Education, Government of Libya for the period of my PhD study.

**15. Who has reviewed this study?**

**East Midlands - Nottingham 1 Research Ethics Committee**, which has responsibility for inspecting all applications for medical research on humans, has examined the proposal of this study and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for inspection by monitors from UCL and NHS UCLH, whose role is to check that research is properly managed and the interests of those taking part are sufficiently protected.

**16. Further Information**

Further information about the study is available from the research supervisors Prof. Paul Ashley (p.ashley@ucl.ac.uk) and Dr. Susan Parekh (s.parekh@ucl.ac.uk) or me the research student Mrs Rema Elhaj-Husian (rema.elhaj-husian.14@ucl.ac.uk).

Unit of Craniofacial Growth and Development, UCL Eastman Dental Institute, 256 Gray's Inn Rd London, WC1X 8LD.

**Thank you for reading this and hope to meet you soon..**

*Please keep this information sheet for your records.*

*If you agree to enter the study, please email us on:*

*rema.elhaj-husian.14@ucl.ac.uk* *and confirm that you would like to be involved in the study.*