**PATIENT INFORMATION SHEET**

**This study is about the acceptability of the local anaesthetic (Wand or traditional) for young dental patients (this will be undertaken as part of a student study and contribute towards an academic qualification).**

*We are inviting your child 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 your child 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. Dentists have been using this method for more than 20 years with their child-patients.

This study was designed to assess the most acceptable technique to give local anaesthetic for the young patients.

We are looking at your child’s opinion about having local anaesthetic for dental treatment using either the normal injection or the Wand. We would like your child to rate his/her experience when he/she comes next time to see the dentist and have dental treatment with local anaesthetic. We hope that the findings will help us answer this question and provide young people with the service that best suits them.

* My name is Rema Elhaj-Husian and I am a PhD researcher and one of the research team.

**2. Why has your child been chosen?**

Your child has been chosen because he/she is 10-16 years of age and requires dental treatment under local anaesthetic.

**3. Does your child have to take part?**

It is up to you and your child to decide whether or not to take part and if your child did not wish to participate even with your consent give, they will not be included in the study. You and your child are free to withdraw at any time and without giving a reason and this would not have any consequences on care or treatment of your child.

**4. What will happen if your child takes part?**

Sometimes we don’t know which way of treating patients is best. To find out, we need to make comparisons between different treatments. To do this, your child will be randomly allocated to 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 (a device used to inject the anaesthetic that is controlled by a computer and is already being used in the dental hospital for children when they need dental treatment under local anaesthetic)

Your child’s dentist routinely performs both of these techniques. Whichever one your child is allocated to will be performed in the usual way by your child’s dentist. The acceptability of each technique will be compared. This is called a randomised study.

**5. What does your child have to do?**

It is a one-day trial and if you and your child agree to take part, we will first ask you to sign a consent form and your child to sign an assent form. The study cannot go ahead without your child’s assent and if you lose capacity to consent, your child will be withdrawn from the study. Involvement in the trial will be about completing questionnaires on the day of your child’s dental treatment appointment. These are specialised questionnaires, recognised as means of assessing children’s acceptability of the local anaesthetic and their level of anxiety. These will all be given to your child on the day before, during and after the appointment. During your child’s dental treatment, he/she will be asked to rate their acceptability of the local anaesthetic just after they’ve received it. There are no follow up visits required for the purpose of the trial apart from your child’s routine treatment.

**6. What are the possible benefits of taking part?**

Your child’s dental treatment will be treated by experienced dentists at the Eastman Dental Hospital using widely recognised local anaesthetic delivery methods. The information we get from this study will help understand child’s acceptability of different local anaesthetic delivery techniques and what make them acceptable.

**7. What are the possible risks of taking part?**

It will take extra time out of your day for your child to complete the questionnaires (10-15 minutes). Otherwise, there are no known risks for children participating in this trial rather that the known risks of the local anaesthetic that will be explained by your child’s dentist during the appointment.

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

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

If you/your child decide to withdraw from the study, you can do so at any time your child’s standard of care will not be affected. We will keep and continue to use all their previously collected data to ensure the integrity of the research in accordance with data protection legislation. We will, however not collect any further data about them. Your child will still be asked to attend the usual follow-up clinics if required by his/her dentist at the hospital. These will not be part of the study.

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

Every care will be taken in the course of this study. However, in the unlikely event that you are injured by taking part, compensation may be available. If you suspect that the injury 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 your research dentist, please make the claim in writing to Prof. Paul Ashley who is the Chief Investigator 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 and on to Sponsor’s Insurers. If you have a claim, then it might be helpful to consult a lawyer. Participants may also be able to claim compensation for injury caused by participation in this study without the need to prove negligence on the part of University College London or another party. You should discuss this possibility with your research dentist in the same way as above. Regardless of this, 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 or about any side effects (adverse events) you may have experienced due to your participation in the study, the normal National Health Service or UCL complaints mechanisms are available to you. Please ask your research dentist if you would like more information on this. Details can be obtained from the NHS website.

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 your child?**

We will need to use information from your child and from his/her medical records for this research project. This information will include:

* NHS number
* Name
* Contact details

Only consent forms will contain your child's name and his/her hospital sticker. The original consent forms will be digitised and stored securely (encrypted) and kept as long as the research data be retained (10 years), permitting the originals to then be destroyed securely by means of shredding. People will use this information to do the research or to check your child’s records to make sure that the research is being done properly. People who do not need to know who your child is will not be able to see his/her name or contact details. Your child’s data will have a code number instead. We will keep all information about your child 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 your child took part in the study. You can find out more about how we use your child’s 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 my child provides?**

We plan to publish the results in a health journal 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 my child’s 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 your child took part in the study.

Once they have finished the 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 will keep it, whether it includes your child’s name, and how long they will keep it.

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

If you agree your child to take part in a research study, you will get the choice to give your child’s research data from this study for future research. This future research will use research data that has had your child’s name, contact details and NHS number removed. Once removed, other researchers won’t be able to contact them to ask them about future research. Your child’s data will not be used to sell them 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 of Eastman Dental Institute at the 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 duration of my PhD study.

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

**East Midlands - Nottingham 1 Research Ethics Committee**, which has responsibility for scrutinising all proposals for medical research on humans, has examined the proposal 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 scrutiny by monitors from UCL and NHS UCLH, whose role is to check that research is properly conducted and the interests of those taking part are adequately 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.**

Please keep this information sheet for your records. If you agree for your child to enter the study, please email us on:

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