Participant Information Sheet for Young People with Sarcoma (13-15 years)

Title of study: Monitoring ototoxicity in patients undergoing treatment with platinum-based chemotherapy for sarcoma and testicular cancer using tablet based self-administered hearing tests

(Student Study)

Department: University College London Hospitals (UCLH) and University College London (UCL)

We would like to invite you to take part in a research project

- Research is a process that lets us find new solutions to medical problems and improve the care we provide our patients
- We are asking if you would take part in research that looks to improve the hearing care we provide to our patients on chemotherapy.
- Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve for you.
- Please take the time to read the following information carefully. Discuss it with family, friends and relatives if you wish. Take time to decide whether you wish to take part.
- Ask us if there is anything that is not clear or if you would like more information.
- If you and your parents decide you would like to take part, then please read and sign the consent form.
- This form demonstrates that you have agreed to take part in the research. Even after signing the form, you can change your mind and stop taking part any time you want.

Contact details of the Co-investigators:

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1. Why are we doing this study?

At the moment we know that some patients who are placed on life saving chemotherapy can suffer with long lasting problems to their hearing. Patients who get hearing loss tell us that this makes it harder to communicate with others and this affects their quality of life.

Unfortunately, now we have no way to predict which patient is at risk of this hearing problem. To pick up the early signs of hearing damage, hearing tests need to be done many times during treatment. These tests need to be done in hospital, take quite a long time, and can be very tiring for patients who are already feeling tired from their chemotherapy.

In our study we are trying to find better ways of predicting hearing damage and an easier way to test patients' hearing during their cancer treatment.

2. Why am I being asked to take part?

You have been invited to join our study because you are about to receive chemotherapy medication that can result in hearing loss. We would like to study better ways to predict and detect this hearing problem.

3. Do I have to take part?

No. It is up to you. If you do, you and your parents will be asked to sign a form giving your assent and consent, respectively. You will be given a copy of this information sheet and your

signed form to keep. You are free to stop taking part at any time during the research without giving a reason. If you decide to stop, this will not affect the care you receive.

4. What will happen to me if I take part?

If you are happy to take part, we will ask you to do hearing tests on iPad, with headphones, at the beginning and end of your chemotherapy treatment, as well as at the beginning and during of each chemotherapy cycle. The hearing test will take around 30 minutes.

We will also measure how well your inner ear is working, using a simple 10-minute test (distortion product optoacoustic emissions or DPOAE). Headphones are placed in one ear at a time and a clicking sound is generated. The headphones have a tiny microphone that listens to the sound the inner ear makes in response to the clicks. The test takes 10 minutes in total and does not hurt.

These hearing tests will be done while you are already in the oncology clinic. We will also ask a few medical questions about whether you have previously taken medications that could have affected your hearing, and we will ask you to complete two questionnaires (Quality of Life and Tinnitus questionnaire) at the beginning and end of your treatment. Each questionnaire will take around 10-15 minutes.

All the hearing assessments in the study are non-invasive and you will be given an opportunity to have breaks at any stage between or during the tests.

We will save some of the blood that is normally taken for your routine care for a new test of hearing loss. This means that no extra needle pricks will be done. This blood will be used to measure a blood protein called Prestin and Otolin-1. This will be done before, during and at the end of your chemotherapy treatment.

As routine standard of care patients undergoing chemotherapy you will receive a hearing assessment at the Royal National Ear Nose Throat RNENT hospital. This will take around 45 minutes.

	Duration of procedure	1st oncology clinic	Hearing testing during treatment (Macmillan Cancer Centre)	End of treatment
Informed Consent	10 mins	X		
Questions about your health and hearing	15 mins	X		

Hearing test at the RNENT & EDH (next door to Macmillan Cancer Centre)	45 mins	X		X
iPad hearing test	20 mins	X	X	X
DPOAE test	10 mins	X	X	X
Blood sample for Prestin and Otolin-1	10 mins	X	X	X
Tinnitus questionnaire	10 – 15 mins	X	X	X
Quality of life questionnaire x 2	10 – 15 mins	X		X

5. What are the possible benefits of taking part?

You will have your hearing evaluated 6 times during your chemotherapy treatment. Your study doctor can let you know the results of these examinations. We will warn you and your consultant if your hearing is starting to become affected.

We hope this study will help doctors learn important information about predicting and monitoring hearing damage during chemotherapy. Our results will also help to develop new drugs that can protect the inner ear during chemotherapy.

6. What are the possible disadvantages and risks involved?

This study carries very little risk to you. In making your decision whether to join this study, you may want to consider:

- Ear discomfort: You will be wearing headphones for up to 30 minutes during the hearing tests. Some people may find the headphones uncomfortable, although they have been used in several research studies and most people have not experienced any discomfort.

- Concern related to hearing loss, ringing in the ears, or loud sounds: You may pay more attention to your hearing as a result of taking part in this study. If you notice changes in your hearing, you may start to worry about how your hearing might change in the future.

If at any time you are upset or distressed by the testing, you can speak to the researcher immediately. You can also withdraw from the study at any point, without giving a reason.

7. What if something goes wrong?

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 you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your research doctor 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 your research doctor, please make the claim in writing to Professor Anne Schilder who is the Chief Investigator for the research and is based at University College London. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

8. Will my taking part in this project be kept confidential?

A copy of this participant information sheet and your signed informed consent form will be placed in a secure place. All the information that we collect from you during the study will be stored at University College London Hospitals and kept strictly confidential and only accessed by authorised members of the research team.

All data collected about you will be anonymised by using participant number numbers which will uniquely identify each individual and be stored in a locked filing cabinet. The anonymised data will also be stored electronically on password protected computers. Identifiable information is only kept for a short period where it is necessary for the conduct of the study.

You will not be identified in any ensuing reports or publications. The research team will occasionally need to allow monitors from Regulatory Authorities to inspect the study paperwork, in order to meet legal, ethical and safety requirements. All individuals who have access to data will be bound by strict data protection and confidentiality rules.

Limits to confidentiality

If during the assessments you tell the researcher something that makes them concerned for your safety, or the safety of others, they will have to share this information as appropriate with the safeguarding team.

9. How will we use information about you?

We will need to use information from you, your medical records, your GP and your oncologist consultant for this research project. This information will include your initials, name, NHS number, contact details.

The research team 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.

10. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you choose to stop taking part in the study, we would like to continue collecting information about your health from your GP and from your central NHS records. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

11.What will happen to the samples I give?

Your blood sample will be destroyed after the analysis of Prestin and Otolin-1 levels is complete at the UCL Cancer Institute. Your blood sample will not be shared or transferred elsewhere.

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13. What will happen to the results of this study?

All your study results will have your personal information removed and then be added to the all other participants' data – this means the results cannot be traced back to you (anonymised). We intend to publish the combined and anonymised results of this study in peer-reviewed scientific journals and a research dissertation. The results will also be used for Asma Awad's (Co-Investigator) doctoral thesis submitted to University College London.

14. Data Protection Privacy Notice

If you consent to take part in this study, the records obtained while you are in this study as well as related health records will always remain strictly confidential . The information will be held securely on paper and electronically at your treating hospital under the provisions of the 2018 Data Protection Act. Your name will not be passed to anyone else outside the research team or the Sponsor, the organisation who is responsible for ensuring that the study is carried out correctly.

Your records will be available to people authorised to work on the trial but may also need to be made available to people authorised by the Sponsor to ensure the researchers have conducted the study safely and to regulations. By signing the consent form, you are permitting the research team access to your anonymised study recordings, in this study and future studies. You are free to withdraw consent and no further recordings will be taken. However, the research team will still have access to your historic anonymised research results.

We will have a duty of confidentiality to you as a research participant. If you withdraw consent from further study treatment, your historic anonymised data will remain on file and will be included in the final study analysis.

In line with the regulations, your data will be archived for a minimum of 5 years from the study end, and no longer than 30 years from study end. Arrangements for confidential destruction will then be made.

You have the right to check the accuracy of data held about you and request that any errors be corrected.

The study is compliant with the requirements of General Data Protection Regulation (2016/679) and the Data Protection Act (2018). All investigators and study site staff will comply with the requirements of the General Data Protection Regulation (2016/679) with regards to the collection, storage, processing and disclosure of personal information, and will uphold the Act's core principles. UCL is the data controller; the UCL Data Protection Officer is [data-protection@ucl.ac.uk]. The data processor is Tanjinah Ferdous

15. Who is organising and funding the study?

This study is sponsored and organised by University College London This study is funded through a research grant from Action on Hearing Loss and the Ministry of Higher Education (Libyan Embassy)

16. Who has reviewed the study?

An independent group of people, called the Research Ethics Committee have reviewed the study's concept, design, and methods in order to ensure that it is safe and that your rights, well-being and dignity are not compromised in the course of the study being carried out. This study has been reviewed and given a favourable ethical opinion by the (**London - Camberwell St Giles Research Ethics Committee**

17. Where can you find out more about how your information is used?

You can find out more about how we use your information

1. at www.hra.nhs.uk/information-about-patients/
2. at www.hra.nhs.uk/patientdataandresearch
3. by asking a member of the research team
4. by sending an email to the UCL Data Protection Officer at data-protection@ucl.ac.uk].

18.Contact for further information

Chief Investigator
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Thank you for taking the time to read this information sheet and to consider this study.