University College London Hospitals NHS
NHS Foundation Trust

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Participant Information Sheet for Sarcoma Group Adults

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

- 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 friends and relatives if you wish. Take time to decide whether or not you wish to take part.
- Ask us if there is anything that is not clear or if you would like more information.
- If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your patient notes, one will be filed with the study records and one may be sent to the Research Sponsor.

Contact details of the Co-investigators:

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1. Why are we doing this study?

In previous studies, it has been shown that platinum-based chemotherapy can damage your hearing. This is called ototoxicity.

In this project we will investigate how often ototoxicity occurs and how severe this is on your hearing. The hearing assessments will take place between your chemotherapy cycles.

We will also be looking at whether the blood proteins (prestin and Otolin-1) can predict whether you will develop a hearing loss during your chemotherapy treatment.

2. Why am I being asked to take part?

We have invited you to take part in this study because you will be required to take ototoxic medication for your cancer treatment. We would like to carry out this study to find out how your age/sex can influence how ototoxicity occurs and how severe it is.

3. Do I have to take part?

No, taking part is entirely voluntary. 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 will be asked to sign a consent form at the start of the study.

You should make your decision only after:

- A research staff member has explained the study to you
- You know the purpose of the study and the risks
- You are willing to do what is asked of you in the study

You can withdraw from the study at any time. You do not have to give a reason. On the other hand, the research team may decide that continuing participation in the study is no longer in your best interest and you may be withdrawn from participation.

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

If you are happy to take part, and are satisfied with the explanations from the research team, you will be asked to sign a consent form which will be co-signed by the study co-

investigator. You will be given a copy of the consent form for your records. At this point the study co-ordinator will also ask you if you would like your primary care team/General Practitioner to be notified about your involvement in this study and any subsequent test results obtained in the course of this study including any important findings. If you wish, the study co-ordinator will discuss with you any findings obtained in the course of the study. With your permission these will be shared with your primary care team/General Practitioner. Whether you decide to participate or not in this study this will not affect your treatment options in anyway

We would need to test your hearing before and during each platinum chemotherapy cycle you will receive and at the end of chemotherapy. This will be done while you are already in the oncology clinic. You will perform the hearing test on an iPad provided. We will take a brief medical history to include previous exposure to ototoxic medications and a history of hearing problems.

We would also measure how well your inner ear is working, using a DPOAE test (distortion product optoacoustic emissions). You can find the description of the tests at the end of this document.

We will ask you to complete two questionnaires (Quality of life questionnaires and Tinnitus questionnaires) at the beginning and after completing your treatment to find out the problems any hearing loss may be causing you and to measure any problems you may have associated with tinnitus. Each questionnaires will take around 10-15 minutes. We will also ask you to complete a (repeat) identical set of Tinnitus questionnaires during your visits if you complain from tinnitus during treatment course.

All the hearing assessments in the study are non-invasive and form part of the standard clinical evaluation currently in place in the NHS. You will be given an opportunity to have breaks at any stage between the tests.

We will also take prestin and Otolin-1 (blood proteins) measurement from a blood sample. This will be done before, during and at the end of your chemotherapy treatment.

	1st oncology clinic	Study visits during treatment (Macmillan Cancer Centre)	End of treatment
Informed Consent	X		
Medical history and background information	X		
Full audiological assessments (Royal National Throat Nose and Ear Hospital)	X		X

Tablet based self administered hearing test	X	X	X
Portable DPOAE assessment	X	X	X
Blood sample for prestin and Otolin-1	X	X	X
Tinnitus questionnaires	X	X	X
Quality of life questionnaires	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. There is no other benefit for you for your participation.

We hope this study will help researchers learn important information on ototoxicity and allow researchers to prepare for upcoming trials of promising new drugs that can protect the inner ear in cancer patients undergoing platinum based chemotherapy.

Also, the study will also produce important information on the use of prestin and Otolin-1 in monitoring ototoxicity, which can inform treatment opportunities and decisions to protect hearing.

6. What are the possible disadvantages and risks involved?

There is relatively little risk to participants. The following have been identified as potential issues of concern for individuals who are deciding whether to join this research effort:

- 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 participating 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 course of 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 able to 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 and contact details.

The research team will use this information to do the research and 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 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 destroyed after the analysis is complete at the UCL Cancer Institute. You will be consented to use your donated sample to use for specific test (Prestin and Otolin-1 test) and there will be no future storage or use of your sample after the analysis. Your blood sample will not be shared or transferred elsewhere. The result information will be shared through publication and professional conferences. The results will also be used for Asma Awad's (Co-Investigator) doctoral thesis submitted to University College London.

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

We intend to publish the results of this study in peer-reviewed scientific journals and a research dissertation. All results will have your personal information removed so you cannot be identified in any published articles.

13. 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 remain strictly confidential at all times. 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. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it, even if you withdraw from the current study.

We will have a duty of confidentiality to you as a research participant. If you withdraw consent from further study treatment, your 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 processors are [Mark Sladen].

14. 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)

15. 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

16. Details of hearing tests performed during the study visit

Test/ Procedure	***Test duration***	***Test description***
Medical history and otoscopic examination by study co-investigator	15 min	History of hearing and general medical problems, examination of the ears.
Pure tone audiometry	15 min	Standard hearing test of inner ear hearing function
Otoacoustic emissions	10min	Responses of inner ear hair cells recorded in response to sounds presented to each ear
Blood test for Prestin and Otolin-1	5 min	An extra 5 ml of blood will be collected for prestin and Otolin-1 analysis along with other blood samples of routine blood tests.
Tinnitus questionnaires	10-15 min	A Set of 25 questions which can be self-administered at home or during the study visit- *Tinnitus Functional Index*
Quality of life questionnaires	10-15 min	Set of 2 questionnaires which can be self-administered at home or during the study visit - ***H****earing* ***E****nvironments* ***A****nd* ***R****eflection on* ***Q****uality of* ***L****ife* *Measurement for Adolescents* *- The Hearing Handicap Inventory For Adults (HHIA)*

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
Anne Schilder (student supervisor): a.schilder@ucl.ac.uk

Principal Investigators
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Thank you for taking the time to read this information sheet and to consider this study.