



Department of Investigative Medicine
Imperial College London
6th Floor, Commonwealth Building
Hammersmith Hospital
150 Du Cane Road
London W12 0NN

PATIENT INFORMATION SHEET FOR YOUNG PEOPLE

WITH DELAYED PUBERTY (13 TO 15 YEARS)

We would like to invite you to take part in our research study. Please read this information sheet carefully and talk to your mum, dad or carer about the study.

WHAT IS A RESEARCH STUDY?

A research study is about finding new information about topics that are important to our health. The research may be too early to help you directly, but the information formed during the research could help other children in the future. This information sheet aims to explain the research so that you can decide whether you want to take part in it or not. Please ask us if there is anything that is not clear or if you want to know more.

Before you begin, we want you to know these few important things:

- You can decide if you want to take part.
- You can say "YES" or "NO".
- No one will be upset if you say "NO".
- If you say "YES", you can always say "NO" later.
- You can change your mind at any time.
- We will still take good care of you no matter what you decide.

WHY ARE WE DOING THIS RESEARCH?

Puberty is a time when your body changes to become more like that of an adult. Puberty is a normal process that can take several years from start to finish, but this process can begin at different ages in different boys and girls. It usually starts around the ages of 8 to 13 years in girls and 9 to 14 years in boys.

Hormones are chemical messengers that are made in one part of the body and travel to other parts of body where they can have an effect. Some hormones have a role in puberty such as testosterone in boys and oestrogen in girls. These hormones cause changes to your body at puberty. In boys, these changes may include changes in voice, hair growth under the arms or growth of testicles. In girls, these changes may include breast growth and starting to have periods.



Young people may go through puberty at different times. Some young people go through puberty earlier than others, whereas some may go through puberty later which is called "delayed puberty".

Usually, when puberty is delayed, it could still start normally without needing any treatment. However, some young people with delayed puberty may have a problem producing the hormones needed for puberty. These young people may need treatment to go through puberty.

At the moment, doctors do not have a good way of finding out who will have difficulty producing puberty hormones.

We are studying a hormone called 'kisspeptin' which acts on the part of the brain (called the hypothalamus) which controls puberty. We want to find out if kisspeptin can stimulate puberty hormones in young people with delayed puberty.

We hope that the information produced through this research will help young people with problems of puberty in future to better find out the cause of their delayed puberty.

WHY HAVE I BEEN ASKED TO TAKE PART?

You have been asked to take part because you are aged 13 to 15 years and you/your parent(s)/legal guardian(s) or your doctor is concerned about delayed puberty. We are interested to find out if young people with problems of puberty can make puberty hormones when they are given kisspeptin.

DO I HAVE TO TAKE PART?

You can decide and say "YES" or "NO".

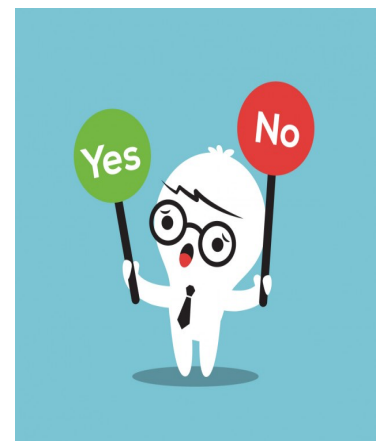
No one will be upset if you say "NO".

If you say "YES", you can always say "NO" later.

You can change your mind at any time.

We will still take good care of you no matter what you decide

It is your choice to decide whether you want to take part. Even if you say 'yes', you can change your mind in future.





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Before you take part in the study:

- You will be given this information sheet to explain about the study. You can think about the research, discuss with your parent(s)/legal guardian(s) and decide whether you want to take part in the research.
- If you want to take part, you will be asked to sign a form to say that you agree to take part (called an assent form).

You can stop taking part in the research at any time you want. If you decide to stop, this will not affect the care you receive, and nobody will be upset if you change your mind.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

If you and your parent(s)/legal guardian(s) are interested in taking part in the research, we will offer you this information sheet to read through during a screening visit. Following that, we will invite you to our study visits at the hospital. You will be asked to attend 2 study visits that will take place on different days within 2 months of each other. If possible, we will try to organise the study visits on school holidays. However, if this is not possible, we can arrange the study visits on weekends so that you will not miss your school days.

Screening visit

On the day of the screening visit, we will begin by explaining the study and answering any questions that you or your parent(s)/legal guardian(s) may have. If you and your parent(s)/legal guardian(s) are happy with the explanation of the study and the answers provided, we will ask you to sign a form saying that you agree to take part (called an assent form) and your parent(s)/legal guardian(s) will be asked to sign a consent form.

We will then ask you and your parent(s)/legal guardian(s) some questions about your health and stage of puberty and we will carry out a general examination of the body to make sure you are healthy. If you are a girl, we will ask you for a urine sample to make sure you are not pregnant and it is safe to take part in the research. If any unknown illness is found out during the visit, we will inform your GP and you may not be suitable for the study.

Study Visit 1

If you are fit and well on the study day and are happy to proceed, we will put a small plastic tube in the vein which is called a 'cannula'. The cannula will let us take blood tests and give the hormones without



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having any more injections. Inserting the cannula will involve an injection that may be uncomfortable, so before we insert the cannula, we can use a special cream / spray on the area to reduce the discomfort. Once the cannula is in place, you will receive a hormone called "GnRH" through the cannula which is a routine test used to test your body's ability to make the hormones needed for puberty. This hormone is not known to cause any side effects. After that, we will take blood tests through the cannula up to 3 hours. Two doctors will be present throughout this period. We will also be measuring your blood pressure and heart rate every 30 minutes during this time to ensure you are well. The whole study visit (including the initial discussion) will last about 5 hours.

You can eat and drink throughout this period, play games or watch a TV/tablet, or read if you wish. We will ask your parent(s)/legal guardian(s) to provide you with snacks/food and drinks. Once we have taken the blood samples, the study is over, and you will be given an Amazon voucher to thank you for taking part in the study. After the visit, you can do everything you would normally do.

Study visit 2

We will invite you to attend the research unit for our second study visit on another day within 2 months of the first study visit. Before you attend the study visit, you can eat and drink as normal and your parent(s)/legal guardian(s) can come with you. We will encourage you to rest well, drink plenty and have a good breakfast on the morning of the study visit.

On the study day, you will be asked to arrive to our research unit in the morning. On arrival, we will insert a small plastic tube or "cannula" in your vein as in the first study visit. We will use a special cream/spray on the area of the cannula to reduce any discomfort that you may feel. Once the cannula is in place, we will take some blood tests through the cannula and another hormone called "kisspeptin" will be given through this cannula. This hormone is not known to have any side effects. Just like in your first study visit, we will continue to take blood tests through this cannula every 10 minutes for up to 8 hours. We will continue to measure your blood pressure and heart rate to make sure that you are well during this time. You can eat and drink throughout this period and play games or watch a TV/tablet, or read if you wish. We will also ask your parent(s)/legal guardian(s) to provide you with the snacks/food and drinks.

WILL THE STUDY HELP ME?

No, there is currently not enough information about how kisspeptin stimulates hormones for the research to help you directly. However, the information produced from the study will help doctors treating young people with disorders of puberty in the future.



WHAT SIDE EFFECTS MIGHT I HAVE IF I TAKE PART?

You may feel some discomfort when the cannula is being inserted. However, we will be offering a cream or spray to reduce the discomfort felt during the process.

When the cannula is removed, it may leave a small bruise. We will also apply pressure on the location of cannula insertion to reduce the chance of a bruise forming.

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

We will look at the information that had been collected and find out if using kisspeptin could be used in future to help young people with disorders of puberty.

WHAT IF I DON'T WANT TO DO THE RESEARCH ANYMORE?

Just tell your mum, dad, carer, doctor or nurse at any time. Nobody will be cross with you and you will still have the same care as you would normally have.

WHAT IF THERE IS A PROBLEM AND SOMETHING GOES WRONG?

During the study, there will be experienced doctors and nurses checking on you to make sure you stay well. After the study, if there is any problem, let us and your parent(s)/legal guardian(s) know.

If you feel that you are harmed or injured because of taking part in this study, you may have the rights to pursue further and ask for legal action. If you wish to complain, or if you are concerned about the way you have been treated during the study, you can contact Professor Waljit Dhillon (email: kisspeptin@imperial.ac.uk). The normal National Health Care Service complaints mechanisms are also available to you. Taking part in this study will not affect your legal rights.

WHAT IF NEW INFORMATION COMES ALONG?



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Sometimes after a research project starts, new information becomes known. If this happens, the new information will be explained to you and your parent(s)/legal guardian(s) so that you can decide if you still want to continue in the study.

WILL ANYONE ELSE KNOW I AM DOING THIS?

All your information will be kept private. The research doctors will know you are taking part. We will only inform your parent(s)/legal guardian(s) and your GP. Any information about you that leaves the hospital will have your name and address removed so that nobody will know you are taking part in research unless you tell them. If any unknown illness is found during the screening visit, we will have to inform your GP so that appropriate treatment can be started.

HOW WILL MY INFORMATION BE STORED?

Once the study is complete, all information will be kept for 10 years in a locked storage in our department. Only persons who have permission and approval can look at this information.

WILL MY BLOOD BE STORED FOR FUTURE RESEARCH USE?

Sometimes, new research ideas come up after completion of a study. Using blood samples that are already collected allows us to generate more helpful information in research. Therefore, we will ask your permission to store blood samples that were taken from you. We will only store your blood samples in our laboratories on NHS premises for use in future research studies for 3 years if you agree. The stored samples will be given a code number which we allocate to you in the beginning of the study. These coded samples will not have any of your personal information (e.g. your name or your address) and nobody will be able to identify you. We will store the coded blood samples in our research laboratories of Professor Waljit Dhillon at Imperial College Healthcare NHS Trust. We will only release these samples for use in research studies that have already had approval from the Research Ethics Committee.

WILL ANY GENETIC TESTS OR OTHER TESTS BE DONE?

We will be testing your blood for genes to help us understand if these are involved in delayed puberty.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?



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When the study has finished, we will present our results to other doctors and we will put the results in medical magazines and websites. We will give you a summary of the study so that you can find out about the results too.

WHO IS ORGANISING AND FUNDING THE STUDY?

This study is organised by Imperial College London. The study is funded by NIHR.

WHO HAS CHECKED THE STUDY?

Before any research can go ahead, it is checked by a group of people called the Research Ethics Committee. They make sure that the research is safe and fair.

HOW CAN I FIND OUT MORE ABOUT THE RESEARCH?

You could contact the research team in Imperial college London: Dr Ali Abbara or Dr Sophie Clarke or Dr Pei Chia Eng by telephone Tel: 02083833242 or Email: kisspeptin@imperial.ac.uk.

Thank you for taking time to read this- please ask us any questions if you need to.