PARENT INFORMATION SHEET

STUDY TITLE: Childhood Atropine for Myopia Progression in the UK (CHAMP-UK)

Can atropine eye drops slow down the progression of my child's short-sightedness (myopia)?

CHAMP-UK

Your child is being invited to take part in a research study. Please take time to read the following information carefully and discuss it with others if you wish. Before you decide whether you want your child to take part or not, it is important for you to understand why the research is being done and what it will involve. Our team will be available, to go through this information leaflet with you, to help you decide whether or not you want your child to take part and answer any questions you may have. If there is anything that you don't understand, please ask one of the research team to explain this further.

The study is being carried out in a number of university and NHS research facilities across the UK. We would like 289 short-sighted children to take part in our study, which is the first of its kind in the UK.

The first part of this Participant Information Sheet tells you the purpose of the study and a brief explanation of what will happen to your child during the study if you decide to take part. In the second part, we give you more detailed information about what will happen during the study. Please ask if anything is unclear.

Thank you for taking the time to read this Participant Information Sheet.

What is the study about?

Short-sightedness, also called myopia makes objects in the distance, such as the television or the whiteboard in school, look blurred. This is caused by the eye growing too long, something that usually happens while children are also getting taller.

We can make people with myopia see better with glasses or contact lenses, but this doesn't stop their eyes continuing to grow longer and become more short-sighted.

The CHAMP UK study is investigating a type of eye drop called atropine that might help to stop myopia getting worse as you get older. This could mean that your child's eyesight without glasses could stop getting more blurry and also keep their eyes healthier as they get older. Children in China have successfully been using atropine eye drops to slow the progression of short-sightedness for many years now, but this trial is the first of its kind looking at whether atropine will work for children living in the UK.

Why has my child been chosen?

If your optometrist (optician) has given you information about the trial, this is because your child is short-sighted. Whether they decide to take part in the study or not, we would like them to continue to go to their own optometrist for their regular eye tests and glasses and/or contact lens checks.

Does my child have to take part?

It is up to you and your child to decide whether they take part or not. If you decide now that your child can take part, and they also agree, either one of you can change your mind in the future and withdraw from the study. You don't have to tell us why and it won't affect your child's eye care in the future.

We will ask you to sign a form (called an informed consent form) to say that you have agreed for your child to be part of the study. Your child will also be asked to sign a form (informed assent form) to say they are happy to be part of the study. At this time, you will be given a copy of this information sheet and a copy of the forms you and your child have signed.

Is my child suitable for the study?

If you decide you would like your child to take part, the first thing we need to do is to check whether your child is definitely suitable for the study. We will do this by conducting a thorough eye examination like the one the optometrist or eye clinic normally does. It will take about one to two hours. We need to make sure all the children who take part are short-sighted, are not receiving any other treatments for myopia (apart from glasses or contact lenses), have healthy eyes and are in good general health too. We will then notify your child's GP of their participation in the CHAMP UK trial.

What will happen to my child if they take part?

In the CHAMP UK study, we will be comparing eye drops that contain an ingredient (atropine) that we think will help to slow down myopia with eye drops that are only designed to keep eyes moist (referred to as placebo eye drops). This is the best way to see if the atropine eye drops really work. Everyone in the trial will be randomly chosen to have either

the atropine or placebo eye drops. You and your child won't know which drops you are getting and neither will the researchers who you see at the clinic. This type of study is called a randomised, masked, placebo-controlled trial. Most children in the study will get the atropine eye drops (193 children) and a smaller number (96 children) will get the placebo. The drops will need to be put into each eye once daily for two years, it is up to you and your child to decide upon a suitable time to use the eye drops (morning, afternoon, evening or night time), but we ask that the same time is used through out the study. It is possible that the drops may sting a little bit, and make your child's pupils bigger, therefore, bright sunlight could be a bit uncomfortable. The drops could also make their close up vision a bit blurry.

Whether your child is given the atropine eye drops or the placebo, they will still need to continue to wear their spectacles or contact lenses to see clearly.

How often will we need to attend?

Everyone who is able to take part in the study will visit the research centre five times. This will happen every six months for two years. At each visit, we will take some measurements of your child's eyes and test how well they see. These measurements are described below. Then you will be given eye drops for your child and both of you will be shown how to put one drop into your child's eyes once daily.

When your child comes back to the research centre, after they have been using the drops for a few months, we will also ask you and your child some questions about using the drops. We will regularly ask you how you and your child are managing with the drops throughout the study, in case anything changes.

Every six months you will get a new supply of eye drops from the researcher. You will be asked to return all seven bottles whether they have been used or not at the next visit so that they can be destroyed safely. The bottles may also be weighed to see how much of the drops have been used. You will be provided with a larger bottle called a MEMS device that will store the eye drop bottle, this device tells the research team how often the drops have been used. The administration guidelines tells you more about this.

At each visit to the research centre, we will;

- Ask you and your child about your child's medical history, daily activities and lifestyle. We will use a simple questionnaire to find out information about things like reading, sports, computer use and time spent outdoors. At the first visit, we will also ask about your family's history of short-sightedness.
- Measure how well your child sees things far away using letters on a letter chart. They just have to tell us what letters they can see as the letters get smaller and smaller. We will do this while they are wearing their glasses or contact lenses.
- Measure your child's reading speed using a simple reading test which even very young children can do easily. We will time how many simple words they can accurately read out loud from a sheet.
- Measure the length of your child's eye. This is done using a machine called an ocular biometer. Your child will place their chin on the machine's chin rest and look at a spot of light straight ahead and the machine will take several quick measurements of the eye length. Nothing touches the eye and all your child has to do is look at the light and keep

their eyes still. This is a painless procedure and your child will not feel anything.

- Measure the shape of your child's eye and it's components (lens, anterior chamber and vitreous chamber). This is done using the ocular biometer (see above).
- Measure how easily your child's eye focuses on close up objects. For this test your child will wear their glasses or contact lenses and put their chin on a chin rest and look through the autorefractor instrument at a small letter held close to their face. The autorefractor measures the accuracy of the eyes' focus on this letter.
- Measure your child's level of short-sightedness. To do this accurately, we will put an eye drop into each of your child's eyes. This eye drop relaxes the muscles in the eyes and allows us to accurately measure the level of short-sightedness. These drops are used routinely by optometrists for children's eye tests and your child has probably had them before. After 30 minutes, we will measure the amount of short-sightedness with a special machine called an autorefractor. Your child just has to put their chin on the machine's chin rest and look at a picture or letter placed on the other side of the room. These drops cause a short-term increase in pupil size, which may last for 12-24 hours, and make close up vision (through their glasses) blurry for up to four hours, and may make them more sensitive to bright light.
- Measure their height and weight.
- We will also ask your child to answer five questions about his/her quality of life using a standard questionnaire called the EQ-5D-Y

At baseline, 12 and 24 months we will do some extra measurements evaluating:

- How big your child's pupils are. All your child has to do is place their chin on a chin rest, keep their head still and look into the distance for a few seconds. The measurement of pupil size is made by a camera.
- The thickness of the light-sensitive tissues at the back of your child's eye (retina and choroid) using a special type of camera called an 'ocular coherence tomographer'. This special camera is used in many eye clinics and optometry practices and all your child has to do is place their chin on the chin rest and steadily look at a light in the machine for a few moments while the machine takes a picture of the back of the eye. There is no flash of light, so the process is not uncomfortable.

Apart from the eye drops, nothing will touch your child's eyes. All the tests are quick, simple and painless and are routinely used on children and adults in eye clinics in the UK.

Five years after the study starts the research team will send your child a questionnaire by post with a pre-paid envelope to ask some follow up questions on how your child's eyes/eye sight has been since completing the study along with an activities questionnaire similar to the one they will have completed as part of the study. The research team will also provide a questionnaire to be completed by your child's optometerist to determine their current prescription and if your child has experienced any problems or complications with their eyes/eye sight since the study ended.

How long do the visits last?

Your visit to the clinic will last between one and two hours. There will be time for your child to rest between measurements if they need to.

What do I have to do?

Apart from helping or reminding your child to put an eye drop into each eye once daily, you and your child don't have to do anything different to usual. You will be provided with written instructions on how to store and administer the eye drops and what to do if there is a problem. Your child should also keep going to their own optometrist as usual for regular eye, glasses and/or contact lens checks. We will ask you to sign a consent form to say that you agree to your child taking part in the study.

What are the possible disadvantages and risks of taking part?

The eye drops used in this study are expected to be safe and well tolerated. Both atropine and placebo drops have been used in eye care for many decades around the world. Atropine has been used for many years by children in Asia (e.g. China and Singapore) as a treatment to slow the rate at which they are becoming short-sighted. The following side effects are possible from using the eye drops in this study:

- An increase in pupil size (which may make your child's vision a little uncomfortable when it is really bright outside, but they can use sunglasses or a hat to help with this) and a reduction in the ability to focus very close up. We don't think this will be a problem in the CHAMP UK study because we are using very diluted drops.
- Other, less common and rare side effects of atropine include eyes feeling a bit uncomfortable or looking a bit red, an increase in the pressure inside the eye and mild swelling of the eyelids. You will be provided with more information describing what to look out for so that you can take action if you have any worries. The administration guidelines tells you more about this.

The bottles should be stored in a refrigerator, and be kept out of the reach and sight of children as once open, they do not have a child proof cap. If your child accidentally drinks the eye drops, you should seek medical advice.

Each pack contains separate sterile droppers to be used to administer the eye drops. Please be aware that these droppers contain latex.

What are the possible benefits of taking part?

If you are given the low dose atropine eye drops, your child's myopia may not get worse as fast as it would have done without the drops. This may prevent the need for expensive lenses to reduce the thickness of the glasses. Other conditions that can develop in adulthood for those that are short-sighted are more likely to develop in those who have high levels, so keeping it as low as possible is an advantage. If you are given the placebo eye drops there are no particular benefits to your child during the study.

Your help with the study is valuable, whether your child has the atropine eye drops or the placebo eye drops, because it will help us decide whether the atropine eye drops are a useful treatment for myopia for children living in the UK.

What if new information becomes available?

We are using low dose atropine in the CHAMP UK study because this seems to be the best option to slow short-sightedness at the moment. If, during the study we get new information that changes our view, we will tell you about it and discuss with you and your child whether you want to continue or whether you should continue with the study. If you and your child decide to continue in the study, you will both be asked to sign an updated consent form. If your child withdraws from the study, their eye care will not be affected in any way.

What happens when the research study stops?

At the end of the research study your child will stop using the eye drops and will continue to receive normal eye care from their optometrist. At present, the atropine eye drops are only available for use in the study. We are conducting this research to determine if they would benefit children with myopia in the UK. Therefore, if they are shown to be effective, it is hoped that they may become available in the future.

The information we collect will be kept for at least five years after the study is concluded and may be combined with other research studies investigating the use of atropine in children with short-sightened in Ireland and Western Australia to form a meta-analysis. After that, the information we have on computer and on paper will be safely deleted or destroyed.

What if something goes wrong?

Every effort will be made to ensure that no one taking part in this study is put at risk or harmed in any way. Atropine eye drops have been used so extensively for such a long time that they are not an experimental drop – the experimental aspect is in this particular application of the drops for myopia reduction, at a much lower dose than normally used for other purposes. It is unlikely that anything will go wrong as a result of taking part in this study. If you have any concerns about any aspect of this study, you should contact the Principal Investigator (their contact information is given below), who will do their best to answer your questions. If you are still not happy, you can make a formal complaint to <name of local complaints body>.

In the event of suffering some harm or injury as a result of taking part in this study, due to someone's negligence, then you may have grounds for a legal action for compensation but you may have to pay your legal costs.

Will my taking part in this study be kept confidential?

<SITE NAME> will collect information about your child for this research study from the assessments carried out and recorded in the case report form (data collection forms) for this research study in accordance with BHSCT instructions.

<SITE NAME> will keep your child's name, and contact details confidential and will not pass this information to the BHSCT. <SITE NAME> will use this information as needed, to contact you and your child about the research study, and make sure that relevant information about the study is recorded for your child's care, and to oversee the quality of the study. Certain individuals from BHSCT and regulatory organisations may look at your medical and research

records to check the accuracy of the research study. BHSCT will only receive information without any identifying information. The people who analyse the information will not be able to identify you or your child and will not be able to find out your child's name or contact details.

<SITE NAME> will keep identifiable information about you from this study for five years after the study has finished.

When you and your child agree to take part in a research study, the information about their health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your child's information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify your child and will not be combined with other information in a way that could identify your child. The information will only be used for the purpose of health and care research, and cannot be used to contact you, your child or to affect their care. It will not be used to make decisions about future services available to your child, such as insurance.

What are the costs and payments for taking part in this study?

Your child will be given a £10 Amazon voucher to thank them for taking part in this study. You will also be given £10 to reimburse you for travel expenses at each of the five visits to the clinic. You will receive the eye drops free of charge and there will be no cost to you.

What will happen to the results of the research study?

At the end of the study we will tell you which eye drops your child was receiving. We will also tell you what the results of the study were. We hope to do this quite soon after the study ends. We will tell other researchers and the public about what we have found through scientific reports, websites and press releases. Your child's name won't appear in any of the reports describing the study or its findings.

Who is organising and funding the research?

Belfast Health and Social Care Trust (BHSCT) is the Sponsor for this study based in the United Kingdom. We will be using information from your child in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your child's information and using it properly. BHSCT will keep information about your child for five years after the study has finished.

Your rights to access, change or move your child's information are limited, as we need to manage your child's information in specific ways in order for the research to be reliable and accurate. If your child withdraws from the study, we will keep the information about your child that we have already obtained. To safeguard your child's rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your child's information by contacting the Northern Ireland Clinical Trial Unit (NICTU).

The CHAMP UK study is funded by the National Institute for Health Research (NIHR). It is being organised and led by Professor Augusto Azuara-Blanco, a Consultant Ophthalmologist based in Queen's University Belfast. The Clinical Trials Unit coordinating the study is the Northern Ireland Clinical Trials Unit (NICTU), Belfast Health & Social Care Trust.

Who has reviewed the study?

This research has been reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Health and Social Care Research Ethics Committee B (HSC REC B). In addition, the Medicines and Healthcare products Regulatory Agency (MHRA) have also reviewed and approved the study.

Contact for Further Information

Research Optometrist

Name:

Address:

Email:

Phone:

Local Principal Investigator

Name:

Address:

Email:

Phone:

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Thank you for taking time to read this information leaflet