Southampton NIHR Clinical Research Facility

University Hospital Southampton NHS Foundation Trust
C Level West Wing, Mailpoint 218
Southampton
SO16 6YD
Tel: 023 8120 4989
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Participant information sheet

The BLIS study: a feasibility study assessing compliance, acceptability and colonisation with different dosing regimens of the probiotic supplement *Streptococcus salivarius* K12 (Bactoblis®) in adults

Chief Investigator: Professor Paul Little
ERGO number: 52915
IRAS number: 273843

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below and ask questions if anything is not clear or you would like more information before you decide to take part. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

Sore throat due to infection of the throat or tonsils (tonsillitis) is a very common reason for people visit their GP. Many will receive antibiotics, however antibiotic resistance is becoming a major problem, and we need to find ways to prevent sore throat or tonsillitis without using antibiotics.

Recent studies have shown that a probiotic supplement called *S. salivarius K12 (SsK12)* containing 'good' bacteria may be able to prevent throat infections. *SsK12* probiotic supplements has been tested in many studies (involving over 2400 children and adults), and all these studies have shown that they are safe. *SsK12* is now able to be bought commercially in many countries (including the UK). A company called 'Bluestone Pharma' is providing the probiotics for the study (Bactoblis®), and may benefit financially if they are found to be effective.

The reason for doing this study is that we would like to find out what the best dosing pattern of *SsK12* should be. These results will help us design a large clinical trial in the future, to test whether this can prevent sore throats or tonsillitis.

Why have I been asked to participate?

You have been asked to participate because we are looking for healthy volunteers to take part who have suffered from sore throat or tonsillitis in the past

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What will happen to me if I take part?

Initial phone call with a member of the study team

If you consent to taking part in the study, you will be contacted by a member of the research team to confirm you are eligible and answer any further questions you may have. The team will also confirm where to post the study pack, and will arrange for an online video call (via Microsoft Teams) with a member of the study team.

Online video call (via Microsoft Teams)

You will have a short video call with a member of the study team. We anticipate this will take less than 20-30 minutes. The study plan will be re-capped, and you will be given brief training on how to perform swabs of your mouth, and two swabs of the mouth will be taken on camera. You will then be randomly assigned to one of two study groups: 'A' or 'B'.

Short course of Ssk12, and return of self-taken mouth swabs and questionnaires

Starting from the evening of your online video call, you will be asked to take a short course of *SsK12* probiotic supplements (Bactoblis®). The *SsK12* probiotic is a flavoured lozenge with a pleasant sweet taste, and dissolves in 3-5 minutes when held in the mouth. The sweetening agent is isomalt, which is not associated with dental caries (unlike sugar).

The length of this course will depend on the group you have been randomly assigned to:
- Group A: two *SsK12* lozenges at night on days 1, 7 and 14.
- Group B: one *SsK12* daily at night for 14 days.

You will also be asked to perform further swabs of your mouth at intervals over the next 35 days (on days 2, 7, 14, 21, and 35). These can be returned to the study team by post (or by hand if you prefer). We will provide you with pre-addressed envelopes and stamps, as well as packaging for storing the swabs. Short reminder text messages will be sent to you. You will also be sent two short online questionnaires via email or text about your views on the dosing pattern (on days 14 and 35).

Further follow-up

No further follow-up of volunteers is planned once the study has finished. You will be able to contact a member of the research team during the study period if you have any questions about the study, or other problems that they think might be associated with the *SsK12* lozenges. If any concerns do arise, the study team will consider an extra clinical review.

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Am I eligible to take part?

In order to be involved you must be an adult over 18 years of age, and able and willing to comply with the study requirements.

You cannot be involved if you

- Currently smoke (including e-cigarettes)
- Have symptoms of sore throat or another infection at the time of joining the study
- Have a significant disease affecting the mouth, or your immune system, which we think might put you at risk of harm, or affect the study results
- Are on a medication which suppresses the immune system (including oral steroids)
- Are known/suspected to be pregnant or breast feeding
- Plan to use mouthwash during the study

Are there any benefits of taking part?

It is unlikely that you will benefit directly from this study. We hope that the information gained from this study will help inform the development of strategies to prevent sore throat/tonsillitis occurring in children and adults in the future. You may gain some general information about your health as part of this study.

Are there any risks involved?

Streptococcus salivarius K12 supplements

S. salivarius a harmless 'good' bacterium found in the mouth of healthy people. It does not share any characteristics with harmful bacteria that cause infection of the throat. All of the studies of *SsK12* probiotic lozenges show that it is safe and well-tolerated. It can be bought commercially in many countries (including the UK), and is recognised as a safe food ingredient by the United States Food and Drug Administration (FDA). We therefore do not expect *SsK12* to cause any problems or pose any risk to you.

Mouth swabs

Mouth swabs can be a little uncomfortable or cause gagging, but this will resolve quickly and should not be painful or pose any risk to you. You will be shown how to take these mouth swabs yourself by one of our researchers if you agree to take part.

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Expenses and payments

Volunteers will be compensated for their time and for the inconvenience with amazon vouchers. Volunteers will be compensated £15 for the initial online video call. In addition, volunteers will be paid £5 for every pair of mouth swabs they post back to the study team. The maximum individual volunteers will be compensated is £45. Volunteers who withdraw from the study prior to its completion, will be offered financial re-imbursement corresponding to the number of throat swabs returned.

Will my participation be confidential?

Yes, all information that we collect about you will be coded with a study number and kept confidential. The information will be available to the study team, safety monitors, sponsor, and external monitors who can ask to audit or monitor the study. Anonymous information (names and other details removed) may be shared with other researchers, or for training purposes. Any study information held on paper form will be kept in a locked room at Southampton General Hospital, or in electronic form on a secure server. Any information that leaves the site will have your name removed so that you cannot be identified. After the study has finished, any information that has been collected about you will be kept for 10 years, as per University of Southampton policy, after which time any link between you and your information will be removed. Anonymised samples collected during the study may also be kept for future analysis by members of the study team as part of further ethically approved research, after which they will be destroyed.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you are interested in taking part, a member of the study team will discuss the study with you and answer any questions you may have. You will then be asked to sign a consent form. You are free to withdraw from the study at any time without giving a reason.

What happens if I change my mind?

If you wish to withdraw from the study you are free to do so at any time without any further follow-up from the research team. In such an event, we would continue to use any data we collected up to the point of your withdrawal. Your compensation would be paid corresponding to whether a study visit was attended, and the number of throat swabs returned via post.

What will happen to the results of the research?

We intend to publish the results of this study in scientific journals and present the results at scientific meetings. All results in journals and presentations will be anonymous. If you wish, we will send you a newsletter with a summary of the study results when they are available.

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Where can I get more information?

If you have any questions or concerns regarding this research study that you wish to discuss with a member of the study team, please contact us on 023 8155 0108/023 8120 4989
Email: UHS.recruitmentCRF@nhs.net

If you are happy to take part in this study, please follow this link to the online recruitment platform to start the consent process: x

What happens if there is a problem?

If you have any concerns regarding this research study please contact the study team (details above). If you were to fall ill out-of-hours and require medical help we would advise you to first seek the advice of your GP or attend the emergency department.

The University of Southampton is the research sponsor for this study. In the unlikely event of harm during the research study, compensation may be available through the University of Southampton's insurance scheme. If you would ever like further details on this, or have a complaint about the study, please contact the Research Integrity and Governance team:

Email: rgoinfo@soton.ac.uk
Tel: 023 8059 5058

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University of Southampton Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you. Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it. Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose. For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.
To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

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If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).