Participant Information and Consent Form

Alfred Health

Full Project Title:

Investigating the role of nebulised mucolytic therapy during lower respiratory tract infections post lung transplantation.

Co-Principal Researchers:

Benjamin James Tarrant, Prof. Greg Snell.
Associate Researchers:

Assoc. Prof. Anne Holland, Assoc. Prof. Bruce Thompson, Mrs Louise Fuller, Dr Brenda Button, Mr Steven Ivulich.

1. Introduction

You are invited to take part in this research project. This is because you have had a lung transplant and have been diagnosed with a lung infection. The research project aims to find out the effect of inhaled, nebulised medication as part of the treatment of your lung infection and increased sputum production. This Participant Information and Consent Form tells you about the research project. It explains what is involved to help you decide if you want to take part. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local health worker.
Participation in this research is voluntary. If you don't wish to take part, you don't have to. If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- understand what you have read;
- consent to take part in the research project;
- consent to be involved in the procedures described;
- consent to the anonymous use of your personal and health information as described

You will be given a copy of this Participant Information and Consent Form to keep.

2. What is the purpose of this research project?

The aim of this project is to compare inhaled, nebulised dornase alfa to normal, isotonic saline. Dornase alfa is a drug approved for use in Australia in cystic fibrosis to thin mucous. Normal saline is a medication commonly used to help thin mucous. To our knowledge, neither therapy has been scientifically investigated or approved for use post lung transplant. Both therapies are currently used at this hospital to treat lung infections post lung transplant, but we are unsure of their effects beyond patient reports.

Participation in the research project will require performing an initial assessment during the inpatient hospital stay, and three subsequent visits to The Alfred hospital for follow-up assessment both during and on completion of the study. Each assessment session will take around 60 minutes. We will try to do these on days when you are already coming to The Alfred for other appointments. Dornase alfa is approved and registered for use in Australia, Europe and the United States of America to treat cystic fibrosis. However it is not approved in any country to treat patients who have had a lung transplant. Therefore, it is an experimental treatment for lung infections post lung transplant. This means that it must be tested to see if it is an effective treatment for post transplant patients diagnosed with a lung infection who have more sputum. Lung infections have very different effects post lung transplant compared to other diseases. This means we cannot be sure results in other studies are applicable in this patient type.

Overall, 32 adults with lung infections post lung transplant will be taking part in this project through The Alfred.
The results of this study will be used by Benjamin Tarrant to form part of his Master of Applied Science research.
This research has been funded by an Alfred Small Project Grant.

3. What does participation in this research project involve?

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. People are allocated randomly into groups and each group has a different treatment. The results are compared to see if one is better. In this study, there is a one in two chance of receiving either treatment, dornase alfa or normal saline.

Both treatment (dornase alfa) and control (normal saline) study groups involve a once daily administration of the inhaled, nebulised product at a standard dose. All equipment required will be supplied to you at no cost while you are taking part in the study. This is in the form of a small nebuliser pump and handset. Each administration takes approximately 10 minutes. Taking the medication involves pouring a set amount of the liquid into the nebuliser pump, which creates a fine mist that can be inhaled through a mouthpiece. Treatment lasts for 1-month after your initial dose in hospital. There is no requirement for treatment in the follow-up phase, from 1-3 months after starting the study.

There are a number of assessments made throughout the study period. An initial assessment is performed at the beginning of the study. Follow-up assessments are performed at 4 weeks and 3 months after starting the study. This consists of lung function testing and 2 questionnaires, performed at The Alfred. Each assessment will take approximately 1 hour.

Each day you will also be asked to complete a short questionnaire, along with matching your sputum to a colour chart and reporting the amount you clear. This will take approximately 2 minutes to complete. Study staff will also look at your hospital record to collect other important information that will help compare treatments. This will consist of: how many lung infections you need to come to hospital for and the amount of time you spend in hospital; the number of lung infections you have over the study period including those treated out of hospital; how many times you need medication to treat your lung infection and the monitoring of your blood tests. Blood tests will only be taken as per the normal standard of care for you. Study staff will ask you to retain all used and un-used medication packages to help monitor the amount of medication used. These will be collected at each assessment appointment.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study staff or participants jumping to conclusions.

You will not be paid for participating in this research project. All tests and medical care required as part of the research project will be provided to you free of charge. You will have to pay for the treatment medicines according to hospital policy. The price will depend on whether you have concession for medications. A 1-month supply of either medication costs $33.60 full priced, or $5.90 with concession. Medication will be free if you have already reached The Alfred's medication safety net. If you do not know if you have reached this amount please ask one of the study staff.

4. What do I have to do?

Participation in this trial involves no restrictions in normal daily activities or physical exercise. All your normal medications will be continued, with the addition of the inhaled nebulised medication for the 1-month treatment period. Participants will be asked whether there are any factors that may stop them from being available for all assessment points as explained above. If you are already on either of these 2 inhaled medications, this may stop you from participating in the study. Your study staff should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

5. What are the possible benefits?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include the ability to cough and clear sputum easier, an improvement in lung function and a decrease in the impact of lung infections on your quality of life.

6. What are the possible risks?

When first taking dornase alfa, you may experience a change in your voice, cough or discomfort in your throat. Inhaled isotonic saline can cause shortness of breath, a salty taste, cough or tightness in the chest. These side effects are usually mild and short-lived. You will be assessed by study staff and not included in the study if you are at an increased risk of experiencing any side effects. When first taking the medication, an Alfred staff member will supervise you.

The most likely unforeseen event that may occur is that you are deemed to require more intensive treatment for your lung infection with special breathing exercises. Any change in treatment will be based on your symptoms and assessment by the treating physiotherapist, in discussion with the lung transplant medical team. You will return to the normal study treatment if and when it is safe to do so.

7. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at a later stage.
Your decision whether to take part or not, or to take part and then withdraw, will not affect your relationship with the researchers or the Alfred Hospital. The treatment you receive will not be affected by your decision regarding participation in this research project.
Should you decide not to take part in this research project, access to study medications will be based on assessment by the treating medical team and access to any necessary equipment, as occurs in current standard practice.

8. What will happen to my test samples?

The blood tests that study staff will monitor during this research project will already be collected after your lung transplant as routine care. They will help monitor your lung infection. No additional blood tests will be needed if you decide to take part in this study. These results will only be used for this research project. On initial analysis blood test results will be individually identifiable via electronic records to study staff as per standard care. Samples will be destroyed after analysis as per Alfred Pathology protocol. Blood test results used by study staff for the purpose of this project alone will be stored securely in the Physiotherapy Department and coded in such a way that personal information will not be identifiable.

9. What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, Benjamin Tarrant will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your research team will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, Benjamin Tarrant might consider it to be in your best interests to withdraw you from the research project. If this happens, he will explain the reasons and arrange for your regular health care to continue.

10. Can I have other treatments during the research project?

Participation in this study involves a 1 in 2 chance of receiving either medication to help you manage your lung infection. No other inhaled medications used to help you clear your sputum can be used during the study period.
You will be asked to stop any lung clearance exercises for the duration of the study period (3 months). This includes any breathing exercises with or without equipment, which you may already use to help clear your sputum.
As already stated, you can continue to perform whole body exercise (eg: walking, running, cycling, weight training) with no restrictions and there will be no change to your normal medications used to manage your lung transplant.

11. What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing. If you do withdraw your consent during the research project, the relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by study staff up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

12. What happens when the research project ends?

The availability of either the treatment drug (dornase alfa) or the comparison drug (isotonic saline) after completion of the study will be decided by the treating medical team. We cannot guarantee that either medication will be available as an ongoing treatment.

13. How will I be informed of the final results of this research project?

A summary of the overall results of the project will be prepared at the completion of the research project. If you are interested in reading about the results of this study, you can contact Benjamin Tarrant who will provide you with a summary copy of the project results, alternatively if you would like a copy of the results sent to you on completion of the project please tick this box. ☐
If you would like details regarding your performance on any of the individual assessment tasks (eg. lung function tests) these can be provided upon request at the completion of the study.

14. What will happen to information about me?

Any information obtained for this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission or in compliance with the law. In any publication and/or presentation, information will be provided anonymously so that you cannot be identified. Information about you may be obtained from your health records held at Alfred Health for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project. Information about your participation in this research project may be recorded in your health records.

During the study, the data will only be accessible to researchers. It will be securely stored in The Alfred Physiotherapy Department and coded in such a way that personal details cannot be identified. At the completion of the project, the data will be archived indefinitely, accessible only to the hospital ethics committee for auditing purposes. You are being asked to provide consent to the use of your data for this project only.

15. Can I access research information kept about me?

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. Please contact one of the researchers named at the end of this document if you would like to access your information. Further, in accordance with regulatory guidelines, the information collected in this research project will be kept indefinitely. You must be aware that the information may become de-identified at some point and access to information about you after this point will not be possible.

16. Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

17. Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of The Alfred.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

18. Consent

I have read, or have had this document read to me in a language that I understand, and I understand the purposes, procedures and risks of this research project as described within it.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project, as described.

I understand that I will be given a signed copy of this document to keep.

Participant's name (printed) ……

Signature **Date**

Declaration by researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's name (printed) ……

Signature **Date**

Note: All parties signing the consent section must date their own signature.

19. Who can I contact?

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

For further information or appointments:

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact co-principal investigator:

Benjamin Tarrant on 03 9076 3450 (b.tarrant@alfred.org.au)

You may also contact the following persons:

Name: Dr Brenda Button
Role: Senior Clinician Physiotherapist – Cystic Fibrosis
Respiratory Stream Leader
Telephone: 03 9076 3450
Email: b.button@alfred.org.au

For Complaints:

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact

Name: Ms Emily Bingle
Position: Research Governance Officer, Ethics & Research Governance, Alfred Health. The Alfred Hospital, Commercial Rd, Melbourne 3004
Telephone: 03 9076 3619
Email: research@alfred.org.au

You will need to tell Ms Bingle the name of one of the researchers above.

Further enquiries and/or complaints can also be addressed to:

The Secretary, Faculty Human Ethics Committee
Faculty of Health Sciences, La Trobe University, Victoria, 3086
Telephone: 03 9479 3583
Fax: 03 9479 5733
Email: health@latrobe.edu.au