Participant Information Sheet

Describing the experience of New Zealanders who have had stem cell treatment for multiple sclerosis

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Ethics committee ref.: 21NTB185

You are invited to take part in a study of the experience of New Zealanders with multiple sclerosis (MS) who have had a stem cell transplant. Haematopoietic stem cell transplant (also called a bone marrow stem cell transplant) is available as a treatment for MS in many countries. Haematopoietic stem cell transplant is not available for treatment of MS in New Zealand. Many New Zealanders have travelled overseas to have this treatment. We would like to find out more about their experience.

Whether or not you take part in this research is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 8 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Taking part in this study is voluntary. You do not have to participate. You may withdraw from this study at any point during the time that the information is being collected. We will remove your information from the study in this circumstance. Any decision to participate, decline to participate in this study or withdraw from the study at a later date will not affect your clinical care.

WHAT IS THE PURPOSE OF THE STUDY?

MS is common in New Zealand. Some people living in New Zealand who have MS have travelled overseas to have a stem cell transplant. We estimate that somewhere between 50 and 100 people in New Zealand have had a stem cell transplant for MS, but we don't know this yet. We would like to collect information about people who have had a transplant. This includes demographic details, the experience of MS before the transplant, the nature of the transplant and experience after the transplant.

Ultimately this research may help to inform decision makers about whether haematopoietic (bone marrow) stem cell transplant becomes available in New Zealand in the future.

HOW IS THE STUDY DESIGNED?

We are hoping that everyone in New Zealand who has had a stem cell transplant for MS will contact us. We don't know how many people are in this group yet.

Taking part in the study will involve completing a questionnaire about your experience. It will also involve giving consent for the study researchers to access your medical records.

WHO CAN TAKE PART IN THE STUDY?

People who have had a bone marrow stem cell transplant for multiple sclerosis can take part.

People who fit these inclusion criteria can take part:

- Were over 18 years old when they had the bone marrow transplant
- Have been diagnosed with Multiple Sclerosis (including all forms of MS such as relapsing-remitting, secondary progressive and primary progressive forms)
- Have had haematopoetic (bone marrow) stem cell transplant for the purpose of treatment of MS. This includes autologous transplant (using your own stem cells in the transplant) and allogeneic transplant (using stem cells from a donor).
- Were living in New Zealand when they had the transplant (and travelled to another country to have this done)

People who fit one or more of these criteria are excluded from the study:

- Underwent treatment stem cells that are not derived from bone marrow, such as adipose tissue derived stem cells
- Underwent treatment with stem cell transplant as part of a clinical trial
- Underwent treatment with stem cell transplant that was funded by an overseas public health system or overseas private insurance (for example because the person was eligible for publicly funded health care in another country)

If you are not sure whether you fit the criteria and are interested in taking part please contact the study researchers.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Taking part in the study will involve completing a questionnaire about your experience. This means that we can collect information about you and about your experience directly from you. The questionnaire can be done online or in paper form. You can choose not to answer one or more of the questions if you do not know the answer or do not wish to share that information. The questionnaire is expected to take 30-60 minutes.

Participation will also involve giving consent for us to access your New Zealand medical records. This is so that we can collect medical information about your MS before and after your transplant. We may access these records by requesting them from your local DHB, general practice, or private medical services.

If you have a copy of your medical records from the overseas hospital where the transplant was done, we will ask you to send us a copy of these. You can send a copy of your overseas medical records electronically or via post.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

The role of the study researchers is purely to collect information about the experience of people who have had stem cell transplants for MS. The study researchers will not make any comment about your clinical care, or about stem cell transplants in general, as this is the role of your clinician. Taking part (or declining to take part) in this study will not impact your clinical care.

Your privacy is important. Data will be stored securely, according to Health and Disability Ethics Committee requirements. Data collected in the study will be analysed and published in a way that does not allow identification of you as an individual.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

The main benefit of taking part in this study is letting others know about your experience.

The information from this study may help New Zealand doctors give advice to their patients about having a stem cell transplant overseas. It may also help decision makers in deciding whether stem cell transplants should be made available in New Zealand in the future.

WILL ANY COSTS BE REIMBURSED?

The financial costs in this study involve your time and any cost of printing/posting questionnaires. There is no financial reimbursement available for this. We appreciate your time and help with the study.

WHAT IF SOMETHING GOES WRONG? (PHYSICAL INJURY DURING THE STUDY)

The information below is standard information included on consent forms for clinical studies. The risk of physical harm in this particular study is very low.

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study, doctors, nurses and other CCDHB staff will record information about you and your study participation. This includes your medical records and answers to questionnaires.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). **Only study doctors and nurses will have access to your identifiable information.**

Rarely, it may be necessary for the study doctor to share your information with other people – for example, if there is a serious threat to public health or safety, or to the life or health of you or another person OR if the information is required in certain legal situations. This scenario is extremely unlikely in this study.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the study doctor. Instead, you will be identified by a code. The study researchers will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The study researchers may have access to your coded information.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Future Research Using Your Information.

If you agree, your coded information (i.e. without information that identifies you personally) may be used for future research related to MS or stem cell transplant. This is optional. If you agree to this please tick the relevant box on the consent form.

This future research may be conducted overseas. If you have given consent in advance, you might not be told when future research is undertaken using your information. Your information may be shared widely with other researchers or companies. Your information may also be added to information from other studies, to form much larger sets of data.

You will get reports or other information about any research that is done using your information in the future.

Your information may be used indefinitely for future research unless you withdraw your consent. Once your information has been shared for future research you will not be able to withdraw it.

Security and Storage of Your Information.

Your identifiable information is held at Capital and Coast DHB during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

Risks.

The following information is included in all clinical research studies. The study investigators consider the risks described below to be minimal.

Although all reasonable efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed.

All care will be taken to represent information collected without social or cultural bias.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

If you have any questions about the collection and use of information about you, you should ask the study doctor.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

You may withdraw your consent for the collection and use of your information, by informing your Study Doctor.

If you wish to withdraw from the study before the data is analysed we will remove your information from the study. When the data is analysed it is 'de-identified' (information such as name and address is removed) so it is not possible to identify individual people. If you withdraw from the study after the data has been analysed, it may not be possible to remove your data from the study. This data will not be in a form where it would be possible to identify you as an individual.

Withdrawing from the study will not affect your clinical care in any way.

CAN I FIND OUT THE RESULTS OF THE STUDY?

Participants will be sent a summary of study results which will be written in plain English. This is likely to be available by June 2022.

WHO IS FUNDING THE STUDY?

There is no specific funding for this study. The study researchers are undertaking this study alongside their clinical work in public Neurology services.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Northern B Health and Disability Ethnics Committee has approved this study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Dikshya Parajuli, Study Researcher
027 393 6053
pardi559@student.otago.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHIC
Email: hdecs@health.govt.nz

Consent Form

Describing the experience of New Zealanders who have had stem cell treatment for multiple sclerosis

Please tick to indicate you consent to the following:

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.		
I have been given sufficient time to consider whether or not to participate in this study.		
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.		
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.		
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.		
I consent to the research staff collecting and processing my information, including information about my health.		
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes □	No □
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.		
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.		
I understand the compensation provisions in case of injury during the study.		

I know who to contact if I have any questions about the study in general.		
I understand my responsibilities as a study participant.		
I wish to receive a summary of the results from the study.	Yes □	No □

Declaration by participant:
I hereby consent to take part in this study.

Participant's name:

Signature:	Date: