

PARTICIPANT INFORMATION SHEET

**STUDY TITLE:** RELY TRIAL

**FULL PROJECT TITLE:** Resection of colorectal liver metastases with or without routine hilar lymphadenectomy - A Randomized Controlled Trial

**LOCALITY:** North Shore Hospital

**PRINCIPLE INVESTIGATOR:**  A/Prof Jonathan Koea

**CONTACT PHONE NUMBER:** 021401901

**ETHICS COMMITTEE REF:** 14/NTB/77

You are invited to take part in a study on the resection of colorectal liver metastases. Whether or not you take part is your choice. If you don’t want to take part, you do not have to give a reason, and it won’t affect the care you receive. If you want to take part but change your mind later, you can pull out of the study at any time. Before you decide whether or not to take part, you may want to talk about the study with family, Ẃhanau, friends or healthcare providers.

This information sheet explains why we are doing the study, what your participation would involve and what the benefits and risks to you might be. Your surgeon or research nurse can explain any words in this information sheet that you do not understand and answer any questions or concerns you may have.

Personal benefits to you may or may not result from taking part in the study, but knowledge may be gained from your participation that will benefit others.

**CULTURAL SUPPORT**

If you require Māori cultural support, talk to your Whānau in the first instance. Alternatively you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext: 2324

If you have any questions or complaints about the study you may contact the Auckland and Waitematā District Health Boards Maori Research Committee or Maori Research Advisor by telephoning 09 4868920 ext: 3204

If you would like other cultural support please contact:

The Asian health support service at North Shore Hospital 4868920 ext 2314

Waitakere Hospital 4868920 ext: 6017

Alternatively ask your research nurse to contact the appropriate service on your behalf.

**WHAT IS THE PURPOSE OF THE STUDY?**

The aim of this trial is to examine whether standard removal of lymph nodes, located near the liver, (called a hilar lymphadenectomy) can delay or even prevent the recurrence of the tumour after resection of liver metastases. It is not proven at the moment whether the routine application of a hilar lymphadenectomy can prevent or delay the recurrence of the underlying disease.

This study will compare two operation procedures. Group A will receive a resection of colorectal cancer liver metastases with hilar lymphadenectomy; this is the experimental treatment group. Group B will receive a resection of colorectal cancer liver metastases without hilar lymphadenectomy, this is the standard treatment procedure (what you would be having if you were not in the study). In order to avoid any bias in the study and give everyone a fair opportunity, the study will be randomized. Randomization is when something is picked by chance, so a sealed envelope will determine the surgery you receive.

The study was set up by Professor Jurgen Weitz, Director of the Department of Visceral, Thoracic and Vascular Surgery at the University of Technology in Dresden, Germany. The study has Ethics approval for Germany, France, Spain and New Zealand.

**WHAT WILL MY PARTICIPATION IN THIS STUDY INVOLVE?**

You have been chosen to participate in this study because you are undergoing an operation to remove colorectal liver metastasis. If you decide to take part you will be asked to sign a consent form. Before surgery your medical and surgical history will be collected. Blood results will be analyzed (the blood taken is part of routine care whether taking part in the study or not so no extra tests are needed). You will be asked to complete a simple questionnaire. If you decide to participate in the trial, an allocation to one of the study groups occurs according to the randomization principle.

After the operation your hospital stay is monitored and documented. On the 2nd and 7th day after the operation your blood will be examined again. If you are assigned to the group with removal of the lymph nodes, data will be collected via routine pathology reports. You will be followed up every 3 months after your surgery by the research nurse via telephone for 2 years. All data collected during the study will be de-identified and sent to Germany for analysis.

Participation will not incur any costs.

**WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?**

The type of surgery you receive will have differences with regard to the intra- and postoperative course (e.g., duration of the operation, blood loss, hospital stay or quality of life). Participation in this study contributes to uncover possible differences concerning the disease-free survival between both procedures after the operation and by this to improve the success of the operation. There are not expected to be any difference in quality of life changes no matter whether you receive the treatment experimental surgery or the standard surgery, but this is not known for sure.

**WHAT IF SOMETHING GOES WRONG?**

If you were injured in this study, which is unlikely, you may be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You would have to lodge a claim with ACC, which may take some time to assess. If your claim was accepted, you may 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 ARE MY RIGHTS?**

Your participation in this research study is voluntary. You have the right to refuse to participate or to withdraw from participation at any time and for any reason. Your refusal to participate or your withdrawal from this study will involve no penalty to you or loss of benefits you would otherwise be entitled to, nor affect your on-going medical care.

Revoking Authorization to Disclose – If you stop participating in this study, you also have the right to revoke (withdraw) your authorization to disclose information. Revoking your authorization means taking back the permission you gave the study surgeon to send information about you to the sponsor. If you revoke your authorization, your surgeonwill not use or release any more information about you after receiving your request, except to tell the sponsor that you have stopped early and have revoked your authorization. However, the sponsor can still keep and use any information that it has already received. Of course the surgery you receive as part of the stude, cannot be revoked.

You may revoke your authorization at any time. However, once you do so, you can no longer continue to participate in the study.

You have the right to access information about you collected as part of the study.

Study information is kept in the hospital in the secure surgical research office. The information will be archived once the study is over and could be kept for up to 15 years.

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

If you have any queries or concerns regarding your rights as a participant in this study, you can contact an independent Health and Disability advocate. This is a free service provided under the Health and Disability Commissioner Act.

Telephone: (NZ wide) 0800 555 050

Free fax (NZ wide) 0800 2787 7678 (0800 2 SUPPORT) Email (NZ wide): advocacy @hdc.org.nz

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study on Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

**WHERE CAN I GET MORE INFORMATION?**

If you have any questions please contact:

1. **Associate Professor Jonathan Koea (Investigator and Surgeon)**

Department of Surgery Ph: 021 401 901

North Shore Hospital Fax: 488 4664

1. **Sherry Nisbet (Research nurse and study coordinator)**

Research Nurse Ph: 09 486 8920 ext: 7233

Department of Surgery Fax: 488 4664

Emai: sherry.nisbet@waitematadhb.govt.nz

North Shore Hospital

**EMERGENCY CONTACT:**

During the study, if you have any questions or if you experience any medical problems, please contact Associate Professor. Koea on 021 401 901. : 09 486 8920 ext: 7233

You should also contact the study surgeon or research nurse if you have been injured or hospitalized for any reason during the study.



INFORMED CONSENT FORM

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| --- | --- | --- | --- |
| Deaf and hearing Impaired  | I wish to have a NZ sign language interpreter.  | Yes  | No  |
| English  | I wish to have an interpreter.  | Yes  | No  |
| Maori  | E hiahia ana ahau ki tetahi kaiwhakamaori/kaiwhaka pakeha korero.  | Ae  | Kao  |
| Samoan  | Ou te mana’o ia i ai se fa’amatala upu.  | Ioe  | Leai  |
| Tongan  | Oku ou fiema’u ha fakatonulea.  | Io  | Ikai  |
| Cook Island  | Ka inangaro au i tetai tangata uri reo.  | Ae  | Kare  |
| Niuean  | Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu.  | E  | Nakai  |

**DECLARATION BY PARTICIPANT:**

* I have read (or have had read to me in my first language), the enclosed patient information sheet and have had sufficient time to consider whether or not to participate YES NO

* I have had the opportunity to discuss this study and to use Ẃhanau support or a friend to help me ask questions and understand the study YES NO
* I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my continuing health care.

 YES NO

* I understand that my participation in this study is confidential and that no material which could identify me will be used in any reports on this study. I understand that sections of my medical records may be looked at by responsible individuals involved in the study including investigators from the University of Technology in Dresden, their authorised representatives, representatives of regulatory authorities or authorised health authorities from other countries or Northern Y Regional Ethics Committee for the purposes of analysing the results or checking that study has been carried out correctly YES NO
* I understand the compensation provisions for this study. YES NO
* I know who to contact if I have any questions about the study YES NO

* I wish to receive a copy of the results of the study YES NO
* I understand that my GP/current health provider, will be informed of my participation in this study and of significant abnormal results obtained during the study and the results of my participation in this study YES NO

I hereby consent to take part in this study.

Patient Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Patient Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**DECLARATION BY INVESTIGATOR:**

I have given a verbal explanation about this study and its procedure to the participant, and have answered the participant’s questions about it. YES NO

I believe that the participant understands the study and has given informed consent to participate

 YES NO

INVESTIGATOR NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

INVESTIGATOR SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SIGNATURE OF INTERPRETER:**

INTERPRETER NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

INTERPRETER SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_