Insert Potential Participant

ID Label



**Participant Information Sheet and Consent Form**

**Person Responsible**

NeuroMuscle

|  |  |
| --- | --- |
| **Title** | Association between acute muscle wasting and functional deficits following severe traumatic brain injury: observational cohort study |
| **Principal Investigator** | Dr. Marc Nickels |
| **Location** | Princess Alexandra Hospital  *Location]* |

*Acting on behalf of the patient, we kindly ask that you read this information sheet about this study. Participation in this research is voluntary.*

Before you decide whether you would like the participant to take part, it is important for you to know why the research is being done and what it will involve. Please take time to read the information carefully. If you wish, please discuss it with family members, friends or your doctor.

Please ask if there is anything that is not clear or if you would like more information. Once you understand the project and if you have no objections to being involved, you will be asked to sign the Consent Form. By signing the Consent Form you do not alter your legal rights, but you indicate that you understand the information and have no objection to your participation.

You will be given a copy of this Patient Information Sheet and Consent Form to keep as a record.

**What is the purpose of this research?**

This study aims to observe muscle loss in patients with a new brain injury over the first 28 days. Acute muscle loss in the first 7 days following brain injury has not been previously studied.

Thisstudy is expected to lay the foundation for future studies to assess the effect of exercise or nutrition on muscle loss and functional recovery following a brain injury.

**What does participation in this research involve?**

Participation in this research involves having the participants thigh muscle size scanned by ultrasound at the participants’ bedside, weekly for the first month after being admitted to hospital.

Routinely collected information will be used to inform muscle size assessments.

At day 28 (post initial baseline ultrasound) or at hospital discharge (whichever occurs earlier) the participant will be asked to complete some routine physical assessments by a physiotherapist. If the participant is reliably following commands these assessments can be completed in approximately 5 minutes.

At 6 months following hospital admission a 5-10-minute follow-up phone call will be made to enquire about quality of life, return to work (if working prior to admission), independence with personal care, and any readmissions to hospital. If the participant remains in hospital at 6 months the interview will be conducted in person.

If a participant is discharged home prior to completing the day 28 ultrasound assessment and could feasibly attend follow-up outcome measurement sessions, they will be asked if they would like to return for follow-up assessments. A $50 gift voucher will be offered to reimburse the participant / carer for the inconvenience of attending an appointment. The costs of parking will be coved with a parking pass to ensure participants or carers are not out of pocket for appointment costs.

There are no costs associated with participating in this research project, nor will you or the participant be paid.

**Does the participant have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish for the participant to take part, they do not have to. If you decide that they can take part and later change your mind, you are free to withdraw them from the project at any stage.

Your decision whether the participant can or cannot take part, or take part and then be withdrawn, will not affect their routine treatment, relationship with those treating them or relationship with the Princess Alexandra Hospital.

**What are the possible benefits of taking part?**

Participants are unlikely to benefit directly from participating in the proposed research project. The research is an observational study that has minimum risks to those opting to participate. Advancements in knowledge that will be able to be attributed to the current study will assist to provide the foundations for further research that can assess the effectiveness of interventions (such as exercise or nutrition or a combination of both) that are likely to lead to improvements in rehabilitation and recovery following a traumatic brain injury.

**What are the possible risks and disadvantages of taking part?**

There are minimal minor risks associated with this study. The ultrasound scans are non-invasive and very unlikely to cause pain or discomfort. The physical assessments are routinely conducted by physiotherapist who are skilled in the assessment of mobility safety. Physiotherapists will only complete an assessment if it is deemed safe to do so.

**Can the participant have other treatments during this research project?**

There are no limitations to other treatments provided to the participant in this study.

**What happens when the research project ends?**

Results of this study will be presented at local, national, and potentially also at international scientific conferences. If possible, a local publicly accessible publication will be completed, for example the PA People newsletter, to assist to disseminate results to the public in lay terms.

If the person responsible or the participant (or the person responsible for the participant) would like to be provided with a summary of the results when the research project is completed, they can notify the appropriate investigator. A copy of the peer reviewed publication will then be posted to the participant.

**Who is organising and funding the research?**

This research project is being led by Dr. Marc Nickels.

This research has been funded by a Metro South Health – Trauma Recovery and Disaster Management grant.

No member of the research team will receive a personal financial benefit from the participants involvement in this research project (other than their ordinary wages).

**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 Metro South Health. The conduct of the research including currency of study approvals, procedures, maintenance of confidential data can be audited at any time by Metro South Research Governance.

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.

**Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if the participant has any medical problems which may be related to involvement in the project (for example, any side effects), you can contact the principal study doctor Dr Matthew Grigg on 3176- 4650 (via ICU administration) or any of the following people:

**Clinical contact person**

|  |  |
| --- | --- |
| Name | Dr. Marc Nickels |
| Position | Senior Critical Care Physiotherapist |
| Telephone | (07) 3176-2401  (24-hour contact, please leave a message out of hours) |
| Email | marc.nickels@health.qld.gov.au |

For matters relating to research at the Princess Alexandra Hospital, the details of the local site complaints person is:

**Complaints contact person**

|  |  |
| --- | --- |
| Name | Sonia Hancock |
| Position | Manager, Research Integrity and Compliance, Metro South Research |
| Telephone | (07) 3443 8046 |
| Email | sonia.hancock@health.qld.gov.au |

Metro South HHS Human Research Ethics Committee (HREC), (EC00167) have approved this study. Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning policies, information about the conduct of the study or the rights of the participant, or if you wish to make a confidential complaint at any time, you may contact;

**Reviewing HREC approving this research** **and HREC Executive Officer details**

|  |  |
| --- | --- |
| Reviewing HREC name | Metro South Human Research Ethics Committee |
| Telephone | (07) 3443 8049 |
| Email | MSH-Ethics@health.qld.gov.au |

Insert Potential Participant

ID Label

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**Consent Form – Person Responsible**

NeuroMuscle

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| --- | --- |
| **Title** | Association between acute muscle wasting and functional deficits following severe traumatic brain injury: observational cohort study |
| **Coordinating Principal Investigator** | Dr. Marc Nickels |
| **Location** | Princess Alexandra Hospital |

**Declaration by Person Responsible**

I have read, or someone has read to me, the Participant Information Sheet in a language that I understand. I understand the purposes, procedures and risks of the research described in the project.

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

I freely agree to the participant taking part in this research project as described and understand that I am free to withdraw them at any time during the project without affecting their future health care.

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

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|  | Name of Participant (please print) | | |  | | | | | |  |
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|  | Name of Person Responsible (please print) | | | |  | | | | |  |
|  |  | | | |  | | | | |  |
|  | Relationship of Person Responsible to Participant | | | | | | | |  |  |
|  |  | | | | |  | | | |  |
|  | Signature of Person Responsible | |  | | | | Date |  | |  |
|  | | | | | | | | | | |

**I consent for this information to be used in future studies with appropriate human and ethics committee approval/s. If so, please tick and sign below:**

Name of person responsible (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Responsible: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_

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|  | Name of Witness: (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature of Witness: |  | | Date |  |  |
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**Declaration by Study Doctor / Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the person responsible for the participant has understood that explanation.

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|  | Name of Study Doctor/ Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
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† A senior member of the research team must provide the explanation of, and information concerning, the research project.

I would like to receive a summary of the study results (lay summary and primary publication).

Yes No

My postal address is the same as the participant’s address before they were admitted to hospital.

Yes No

If no, the best address to send study results to is:

Insert Participant

ID Label

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**Form for Withdrawal of Participation – Person Responsible**

NeuroMuscle

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| --- | --- |
| **Title** | Association between acute muscle wasting and functional deficits following severe traumatic brain injury: observational cohort study |
| **Coordinating Principal Investigator** | Dr. Marc Nickels |
| **Location** | Princess Alexandra Hospital |

**Declaration by Person Responsible**

I wish to withdraw the participant from taking part in the above research project and understand that such withdrawal will not affect their routine treatment, relationship with those treating them or relationship with The Princess Alexandra Hospital.

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|  | Name of Participant (please print) | | |  | | | | | |  | |
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|  | Name of Person Responsible (please print) | | | |  | | | | |  | |
|  |  | | | |  | | | | |  | |
|  | Relationship of Person Responsible to Participant | | | | | | | |  |  | |
|  |  | | | | |  | | | |  | |
|  | Signature of Person Responsible | |  | | | | Date |  | | |  |
|  | | | | | | | | | | | |

**Consent to allow data collected prior to withdrawal to be used for research purposes:**

No

Yes

Date

Signature of Person

*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

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† A senior member of the research team must provide the explanation of, and information concerning, withdrawal from the research project.

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the person responsible for the participant has understood that explanation.

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|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
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