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Participant Information Sheet

Title of Project: Paramedic Analgesia Comparing Ketamine and MorphiNe in trauma: PACKMAN

You have been given this leaflet to read and consider because you were taken to hospital after being injured. The Ambulance Service which treated you is taking part in a clinical trial called PACKMaN.

This information sheet explains the trial and what it means for you. One of our team will go through the information sheet with you and answer any questions you have. We suggest this should take about 20 minutes. Talk to others about the study if you wish and don't be afraid to ask us questions.

Information about the research

Pain after an injury is common. The strongest pain killer that UK paramedics routinely use is morphine. In some parts of the world (Australia, Canada and America) paramedics use a different pain killer called ketamine. Research from these countries suggests that ketamine might be better than morphine, but the research isn't good enough for us to be sure. We need to find out if ketamine is suitable for use by paramedics working in UK ambulance services.

What is the purpose of the trial?

We want to test whether morphine or ketamine is better for treating severe pain caused by acute traumatic injury. The trial is taking place at two Ambulance Service Trusts in England and we are hoping to include 446 people in the trial.

Why am I already in the trial?

When the paramedics treated you for your injury they needed to give you pain relief. You will have received either morphine or ketamine as pain relief from the paramedics. The paramedic will not know which you have been given because the trial is blinded. This is to stop any bias in treatment.

You may remember the paramedics asked you if you were happy to receive either morphine or ketamine when treating you. However, as a result of your injury the paramedics were unable to fully discuss the trial with you at the time. It was also not possible for the paramedics to speak to those close to you and obtain consent as this may have delayed your emergency treatment.

This information leaflet will fully explain the trial and we are now asking your permission to continue the next phase of the research trial.

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What happens next?
A member of the research team will contact you to discuss the trial further.

A member of the research team will ask if you have had chance to read this information leaflet and will ask if you have any questions. They will discuss the trial and information leaflet with you and do their best to answer any questions you may have. There is no rush to decide if you would like to continue to take part in the trial, feel free to discuss the trial with those close to you.

When you are ready and if you do decide that you would like to continue to take part in the trial, the researcher will ask you to sign a consent form. This can be either done online via a weblink, or alternatively a paper form can be signed. You will be given a copy of this consent form, the researcher will keep a copy and the original will be placed in your medical records.

What will happen to me if I agree to continue to take part?
You received the treatment that forms part of this trial at the time of your injury and data about your pain were collected. No further trial related treatments are required.

We would like to follow your recovery progress over the next 6 months.

In order to do this, we will ask you to answer short questionnaires at around 3 and 6 months after your injury. These can be completed and returned in the post or over the telephone with a member of the research team, whichever you prefer. The questionnaires should take each about 15 – 30 minutes to complete.

It is important that we can collect as much information from patients like you, so we will send you a gift voucher with each questionnaire as a thank you, but there is no obligation to complete and return the questionnaires.

We will also ask the hospital you were taken to by the paramedics for information about your stay.

We will inform you of any new information that becomes available, if it is relevant to your participation in the trial.

Will you inform my General Practitioner?
We will only inform your GP of your participation in the trial if you find out you were pregnant at the time of receiving the pain relief. There is no known risk of using either morphine or ketamine during pregnancy, but we will inform your GP should they wish to follow you up more closely.

Do I have to take part?
You do not have to agree to take part. If you choose not to participate in the trial any further, it will not affect the treatment or care that you receive in any way.

You can withdraw from the trial at any time and without giving a reason or affecting your rights. If you stop participating, we will not ask you to complete any more questionnaires and we will not collect any more information about you. We will keep the information already collected prior to you withdrawing from the trial.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. If you agree to take part in this trial, you will have the option to take part in future research using your data saved from this trial.

How will we use information about you? Will my taking part in this trial be kept confidential?
The University of Warwick will act as the data controller for this trial, and are responsible for looking after your information and using it properly. We will be using information provided by you as well as information from your medical records in order to undertake this trial.

NHS ambulance staff will collect information from you and your medical records for this research trial in accordance with the University of Warwick's instructions. We will only use data that we really need to for this research trial.

NHS ambulance staff will use your name, date of birth, NHS number and contact details (address, telephone number and email address) to contact you about the research trial, to:

- contact you about follow-up questionnaires to be completed and to complete any missing information on the questionnaires
- to provide a copy of the signed informed consent form
- to collect data from ambulance service medical records and from the hospital who treated you
- to make sure that relevant information about the trial is recorded for your care.

NHS ambulance staff will pass information collected about you and from your medical records to the University of Warwick using secure methods. Trial data will be held securely and will only be accessible to authorised staff. The only people in the University of Warwick who will have access to information that identifies you will be people who need to audit the data collection process and oversee the quality of the trial.

The data collected from the ambulance service and hospital will include your name, date of birth, NHS number, address, and health information, which is regarded as a special category of information. This health information will include clinical information about your

treatment and stay in hospital, if you were admitted as an inpatient. We will use this information to follow-up on how you recover and to find out the costs of treatment you received.

If you choose to consent online via a weblink, this will be through Qualtrics which is a third-party company. Qualtrics has legal agreements in place with the University of Warwick and has been through strict information security assessment. For further information please see below the links to Qualtrics' privacy statement and more information on data protection:
https://www.qualtrics.com/privacy-statement/
https://www.qualtrics.com/support/survey-platform/getting-started/data-protection-privacy/

The University of Warwick and the ambulance services taking part in the trial will keep information about you for a minimum of 10 years after the trial has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Individuals from the University of Warwick and regulatory organisations may look at your medical and research records in order to check the accuracy of the research trial.
The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

You can find out more about how we use your information here:
https://warwick.ac.uk/services/sim/privacynotices/research/

If you have any query, concern or complaint about our use of your personal data the DPO can be contacted via email at DPO@warwick.ac.uk

Or write to:

The Data Protection Officer

University of Warwick
University House
Kirby Corner Road
CV4 8UW

When agreeing to take part in a research trial, the information about your health and care may be provided to researchers running other research studies at the University of Warwick and in other organisations. These organisations may be universities, NHS organisations or

companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

What are the possible risks of taking part?
The risks from continuing in the trial are small, although receiving a questionnaire or a visit from a researcher could be upsetting. Our trained research staff can talk to you about any such feelings and can offer to put you in contact with professional services if required.

Continuing to be part of the trial will require a modest time commitment to complete the questionnaires.

What are the possible benefits of taking part?
We do not know whether morphine or ketamine is better, and that is why we are conducting this research. We therefore cannot promise any direct benefits as a result of taking part in this trial. However it is hoped that the research will provide benefit to future patients because the information we collect from you will help us determine how best to treat people with severe pain caused by traumatic injury in the future.

What if something goes wrong?
It is extremely unlikely that anything will go wrong as a result of you taking part in the trial because the treatment for your pain, given by the paramedic has already finished. However, if you feel that you have been harmed during your treatment due to someone's negligence, then you may have grounds for a legal action against the relevant NHS organisation, but you may have to pay your legal costs.

What happens if I have any questions, concerns or complaints about the trial?
If you have any questions or concerns about any aspect of this trial, you should ask to speak to the researchers who will do their best to answer your questions [PI contact number].

If you are unhappy about any aspect of your treatment and wish to complain, you can do this through the NHS Complaints Procedure. You can contact the local ambulance service Patient Advice Liaison Service (PALS) or local Clinical Commissioning Group. For more information on the NHS complaints procedure or to find your local contact go to: http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/

If you remain unhappy and wish to complain formally, you can do this by contacting the person below, who is a senior University of Warwick official and is independent of this trial:

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Deputy Director/ Head of Research Governance Research & Impact Services
University House
University of Warwick
Coventry
CV4 8UW
Tel: 024 76 522746
Email: researchgovernance@warwick.ac.uk

This trial is covered by the NHS and University of Warwick's insurance and indemnity cover. Any complaint about the way you have been dealt with during the trial or any possible harm you may have suffered will be addressed.
In the event that you have been harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Warwick or the relevant NHS organisation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

What will happen to the results of the trial?
This trial will take around 3 years to complete. We will share the results of the trial with other healthcare professionals and will publish the results of the trial in medical journals. When any information from the trial is published it will not contain personal information, and it will not be possible to identify you.

We will ensure the results of the trial are shared widely. If you would like a copy of the published results, please contact the trial team (contact details below).

Who is organising and funding the research?
The trial is organised by a group of doctors, paramedics and scientists led by Professor Gavin Perkins, who works at the University of Warwick. Two Ambulance Services are taking part in this trial.

The costs of the trial are being met by the NHS and the National Institute for Health Research (Health Technology Assessment Programme).

Who has reviewed the trial?
All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This trial was reviewed and given a favourable opinion by the West Of Scotland Research Ethics Committee on 1st September 2020. The trial has also been reviewed by the Medicines and Healthcare Products Regulatory Agency (MHRA), Health Research Authority (HRA) and National Institute for Healthcare Research (NIHR) Health Technology Assessment Board.

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How have patients and the public been involved in this trial?
Patients and the public have been involved in designing the trial to guide the research and make sure it is focused on what is important to patients. A patient and public involvement (PPI) group will meet regularly during the course of the trial and will comment and advise the research team on the trial findings. They will help design how the results will be distributed.

Who do I contact for more information?
PI FOR LOCAL SITE NAME, [email].
RESEARCH PARAMEDIC NAME, [email]. Tel: [mobile].
Trial Team at the University of Warwick: Email: packman@warwick.ac.uk Tel: 02476 150478

Thank you for reading this information leaflet