TRUST HEADED PAPER

Obeticholic Acid for the Amelioration of Cognitive Symptoms trial – 3 (OACS-3)

Participant Information Sheet v7.0 22/11/2023

INVITATION

We are inviting you to take part in a research trial called OACS-3. This information sheet tells you more about why it is being done and what it might mean for you. Please read the following information carefully to help you decide if you want to take part. You don't have to decide straight away, and you may want to talk to your friends and family before making a decision. Ask the trial team if you have any questions or you want to know more.

KEY POINTS

- This trial is looking to see whether a drug called Obeticholic Acid is tolerated and safe for people with Parkinson's, as well as looking to see if it has any effect on memory and thinking.
- Obeticholic Acid is used widely in the treatment of a liver condition called Primary Biliary Cholangitis, where it has been used safely for a number of years.
- We are hoping to recruit 25 patients in total as this is a small pilot study.
- If you decide to take part, you will be randomly given either a 'dummy' drug (placebo) or the treatment drug Obeticholic Acid. You will have a chance of 1 (placebo) to 1.5 (Obeticholic acid) of being in each group.
- Your trial doctor and the trial team will not know which drug you are taking.
- You will have a screening visit to assess whether you meet the criteria for the trial.
- During the trial, you will have regular visits and calls so that we can check how you are doing and review your trial medication. We will take regular blood samples.
- You will also be asked to complete a participant diary to help track your medication use and several questionnaires of which some you can complete at home.

Please read the following information for further details about the trial if you are interested in taking part and see page 16 for contact details

OACS-3

PARTICIPANT INFORMATION SHEET

Why is OACS-3 needed?

This research aims to see whether treatment with Obeticholic Acid improves memory and thinking and fatigue (tiredness) symptoms and whether it is safe and well tolerated in people with Parkinson's (PwP). If the results from this small trial show that the treatment might be effective, it could lead to a larger clinical trial.

The development of memory and thinking problems in PwP is common and has a big effect on patients and carers. At present, there is little in the way of treatment for this. There has been increasing interest in drugs used in other medical conditions that might also have an effect in Parkinson's. One such drug is Obeticholic Acid, which has been used in liver disease (specifically in a disorder called Primary Biliary Cholangitis) and may improve memory and thinking.

Using drugs that are already in clinical use for other conditions is an effective way to ensure patient benefit is seen in a timely manner. There is an overlap in symptoms in liver disease and Parkinson's – symptoms such as fatigue and memory and thinking problems. We know from other research that there might be a similar underlying mechanism of thinking problems in patients with both liver disease and Parkinson's. For example, bile acids, which are made in the liver, change function in liver disease as well as with age and with Parkinson's. Animal studies have shown that treating ageing mice with Obeticholic Acid improves symptoms such as memory changes. If this current study demonstrates some improvements in measurements, it will be a very exciting field of research where little treatment currently exists.

Why have I been invited to take part in OACS-3?

You have been invited to take part because you have been diagnosed with Parkinson's and may have mild memory problems. You are aged between 18 and 79 (inclusive) and your clinical team think that you could meet the criteria to take part.

Do I have to take part?

No, it is entirely up to you to decide if you want to take part. If you choose not to, you will continue to get the normal (standard) treatment arranged by your doctor.

If you agree to take part, you can change your mind and withdraw from the trial **at any time** without having to give a reason. Your future care will not be affected in any way.

Given the current coronavirus pandemic, is it safe for me to take part?

We can reassure you that the trial will follow all recommended COVID-19 local and national guidelines and all required COVID-19 safeguards will be used.

If it is necessary, several participant questionnaires may be sent to your home ahead of your study visit to complete at home or via telephone. We would then ask you to bring the completed questionnaires to your next trial visit or post them to us using pre-paid envelopes that will be provided to you. Your local trial team will be in touch with you before arranging any face-to-face visits, which will follow the most up to date guidance on social distancing. If you have any questions, at any time, about this trial and coronavirus please speak to your local team. Their contact details are listed at the end of this document.

What will taking part involve?

Taking part in this study involves attending 10 trial visits over 6 months. Some of these visits will be at hospital appointments and some will be over the phone.

If you are interested in taking part in the trial, you will be invited to a trial visit where someone from the research team will go through this information sheet, answer any questions you may have and ask you to complete a consent form to confirm you would like to take part in OACS-3. You'll then have some assessments to confirm whether or not you can take part. If it's found that you are not able to take part, you will continue to receive the usual NHS medical care that you would receive outside of the study.

Trial Medication

If you take part in OACS-3, you will receive either Obeticholic Acid or placebo tablets. A placebo is a dummy drug that looks the same as the real one but is a harmless substance that has no effects. Out of the 25 people we plan to take part in this trial, around 10 patients will receive placebo and around 15 patients will receive Obeticholic Acid. To keep the trial fair, which of these you receive is decided randomly by a computer, which is a bit like flipping a coin. You will not be able to tell which medication you are taking.

Your doctor and trial team will not have any say on which group you are in nor will they be aware of which medication you have been given. The medication you are taking will remain unknown unless there is a clinical reason or emergency which means this information is needed for your safety.

You will be treated with Obeticholic Acid or placebo tablets for 26 weeks (around 6 months). You will have your final trial visit or call approximately 4 weeks after you finish your trial medication. Your total time on the trial will be around 30 weeks. If you feel unwell while taking the medication, you can contact the trial team to discuss this at any point during the trial.

The trial team will monitor you throughout the trial to check how you are doing when you are on trial medication. You will be asked to have two MRI scans, give blood samples and complete a series of questionnaires and assessments during your involvement in the trial. If you are unable to have the MRI scans, or you do not consent to them, you are still able to participate in this trial. Details of the MRI scans are given below:

MRI

MRI stands for Magnetic Resonance Imaging. MRI is safe and has no known side effects. It uses a large magnet, radio waves and a computer to form an image of your body. MRI scans offer a safe and efficient method for medical diagnosis of many conditions, without the use of x-rays. You cannot have an MRI if you have implantable devices, such as a pacemaker, metal heart valves, or clips on the brain. The study team will check for any contraindications.

The equipment may look intimidating but there is no need to be nervous. The MR scanner is a large well-lit tunnel, which is open at both ends. The tunnel remains open and you are never totally enclosed. You will normally lie flat on your back and be moved into the tunnel on a sliding couch. Please see further down in this information sheet for more information.

The scanning time usually ranges from 30 minutes to up to 1 hour and will take place at the Newcastle Magnetic Resonance Centre based at the Campus for Ageing and Vitality (based on the West Road in Newcastle upon Tyne).

If something is found as part of the MRI scans that may need further investigation, the MRI team will pass this information onto your clinical team to follow up with you.

The data collected from the MRI assessments will be used in the analysis of this trial. With your permission, we would also like to use the data collected from these assessments for future analysis and research. Research carried out on this data will not identify you, as the information will be linked to a unique trial identification number instead of your name.

Memory and Thinking Assessments

As part of the trial, you will also be asked to complete some straightforward memory and thinking tasks, some of which involve pencil and paper and some of which are computer based (CANTAB tasks). Don’t worry if you don’t have experience with computers, as the tests are simple and merely involve touching a screen to make a response. There will be someone with you to assist at all times, and part of the visit will include time to familiarise yourself with this.

The data collected from the computerised assessments will be used in the analysis of this trial. With your permission, we would also like to use the data collected from these

assessments for future analysis and research. The information collected will be linked to a unique trial identification number instead of your name. CANTAB tasks also require that we collect your date of birth and sex, both of which are classed as identifiable data.

Walking (Gait) Assessment – Only for participants recruited at Newcastle upon Tyne Hospitals NHS Foundation Trust

We will perform an assessment of your walking, where you will walk for 2 minutes over a 25-metre oval circuit which includes a pressure sensitive mat to detect your steps. We will also ask your permission to record a video of your walking, but this is optional. Please note that we may use the video of your gait in presentations at scientific meetings but this will be completely anonymised and you will not be recognised from this video unless you state otherwise. The video files will additionally be labelled with your unique study identification number and stored on a password protected computer servers only accessible to the study team.

We will also ask you to wear a small, lightweight body worn sensor on your lower back during walking.

Axivity Monitoring

As part of the trial, we will ask you to have a small activity monitor (23 x 32.5 x 8.9mm) attached to your lower back and worn for seven (7) consecutive days (including at night). This will be at the beginning of the trial and near the end of the trial. There are no switches or buttons on the monitor; it will remain 'on' for the full duration. It is also waterproof so can be worn whilst bathing and showering. After the 7 days, you will remove the monitor and post it back to the research team in a prepaid envelope.

The axivity monitor is a device that measures a person's gait (the way you walk) and activity. It will capture information about things such as the length of your steps, the number of steps you take per day, how long you spend active and how fast you are walking, amongst other things. All data collected by this device will be stored on the device itself and then downloaded by the research team.

We will provide you with detailed instructions with pictures on how to attach the monitor to your back and on how to return the monitor back to us.

Questionnaires

We will ask you to complete several questionnaires at predefined time points as listed in the Trial Visits section in this patient information sheet. These questionnaires will help us understand how you are feeling, how your symptoms may be changing throughout the trial and whether we need to take any further actions with regards to your care.

If your answers collected from the Hospital Anxiety and Depression Scale (HADS) questionnaire show that you may have high levels of anxiety or depression, we will let

your GP know about this as well as anyone else in your care team who might need to know.

Trial questionnaires completed at visits 2, 6, and 9 are the most time consuming and will take you over an hour to complete. To make this easier for you and to limit the time spent at the visits, we may send some of your trial questionnaires to you to be completed at home rather than in person at your trial visits. Your trial team will discuss this option with you and confirm you are happy for this to happen.

There are also some assessments and one questionnaire that we will ask if someone you live with or cares for you would be happy to complete. If they are, we will provide them with a patient information sheet (like this one) and a consent form to complete to show they are happy to take part.

At the end of the trial, we will also ask you to complete a post trial questionnaire and your direct quotations may be used when we publish the results but you will not be identifiable from this data.

Patient diary

You will be given a diary to record the dose of trial medication you have taken, any other medications you may be taking and any missed doses. We will also ask you to record any symptoms or medical events you may have had (anything from headaches to breaking a bone). The trial team will then go through this with you when you attend your visits.

Trial Safety Card

You will be given trial safety card giving details of who to contact if you have any problems or issues during the trial. If you attend any hospital or clinic treatment appointments outside of your OACS-3 visit schedule, please always show your trial safety card to the treating clinician.

Blood Samples

As this is a safety study, we will be checking routine safety bloods (including a full blood count, kidney test, liver tests, cholesterol) at six (6) of the study visits (screening visit, visits 3, 4, 6, 9 and 10). This will be around 2 tablespoons of blood at each of these visits. These routine safety bloods will be analysed in the hospital laboratories, just like they are in routine care. These samples will then be destroyed in line with local NHS site policies.

As part of the trial, we will also ask if you would like to give some optional additional blood samples. These will be stored in a biobank and used for this trial as well as further research.

There are 2 different biobank samples we would like to collect:

- **Biobank samples** (stored at the Newcastle University Medical School)
    - 3 samples: Baseline visit (visit 2), visit 6 and visit 9
    - Around half a tablespoon of blood at each visit

- **Parkinson's Specific Biobank samples** (stored at the Campus for Ageing and Vitality; the former Newcastle General Hospital site)
    - 2 samples: Baseline visit (visit 2) and visit 9
    - Around half a tablespoon of blood at each visit

If you consent to these additional optional samples, these will be taken by someone on the research team at your trial visits. Researchers who will analyse these samples will not know your identity and the samples will only be identified by a pseudonymised code. Consent for these additional samples is optional and you can still take part in the trial without providing these samples.

Additional data linked to the biobank samples will be collected and stored in the trial database. This will include the time the biobank sample was taken and for some of the samples, we will ask the last time you ate before the biobank sample was taken

These samples will be processed and stored at either the Newcastle Biobank (at the Newcastle University Medical School) or the Biobank at the Centre for Ageing and Vitality (CAV). The biobanked samples and linked data may then be used in further research or further research and analysis linked to the OACS trial programme by researchers, including the trial funder (Intercept Pharmaceuticals).

You will be given a unique trial identification number instead of your name being written on trial documents. Only the trial team at the hospital will be able to link this number back to you using your date of birth, name and NHS Number. This means your data will be pseudonymised.

Pregnancy

To take part in the trial, women must not be pregnant, breast-feeding or be planning a pregnancy during the time of the trial and for 30 days after taking the last dose of the trial drug. This is because we do not know the effect of the trial medication during pregnancy. To prevent pregnancy during the trial, all women who could become pregnant have to either practice sexual abstinence in line with their preferred and usual lifestyle, or use what is called an 'acceptable effective' method of contraception.

These methods include:

- combined hormonal contraception (oral, intravaginal, transdermal)
- progestogen only hormonal contraception (both those that do and do not have inhibition of ovulation as the primary mode of action)
- intrauterine device (IUD)
- intrauterine hormone-releasing system (IUS)
- vasectomised partner
- bilateral tubal occlusion
- male or female condom with or without spermicide
- cap, diaphragm or sponge with spermicide
- sexual abstinence

*Please note periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception.

If you are a woman who could become pregnant, we will ask you to take a pregnancy test at your screening visit. This is to ensure that you are eligible to participate in the trial.

If you become pregnant during the trial, you should stop taking the trial drugs and tell your trial doctor or research team **immediately**. If this happens, your pregnancy will be followed to its outcome (for example, until you have your baby). We will ask you as part of the consent process to confirm you are happy for the research team to follow any pregnancies to completion. The pregnancy follow up would include regular telephone calls to you to check how you are feeling and to check if you are experiencing any issues.

What if my partner becomes pregnant while I am on the trial?

If your partner becomes pregnant during the trial, you will need to notify your trial doctor or research team. If this happens, we will ask your partner to give permission to follow up on their pregnancy to its outcome. The pregnancy follow up would include regular telephone calls to your partner to check how they are feeling and to check if they are experiencing any issues.

Trial Visits

If you meet the criteria and decide to take part, you will be asked to attend up to ten visits (some of these will be over the phone).

Visit 1 - Screening Visit

This visit will include the following:

- Complete a consent form to confirm you are happy to take part in the trial
- Going through your medical history and any medication you take
- A clinical examination
- Have a blood pressure and pulse check
- An electrocardiogram (ECG)

- Complete two brief paper memory assessments (MoCA, verbal fluency) and an examination of your Parkinson's (MDS-UPDRS)
- Provide a blood sample to check you are eligible to be on the trial
- If you are a woman who could become pregnant, you will need to take a pregnancy test
- Practice run through the CANTAB assessments
- Check if you are having any symptoms

Your doctor will then use this information to confirm if you are eligible to take part in the trial.

As part of this visit, a member of the trial team will also attach the Axivity activity monitor to you to collect your activity data for the next 7 days. The trial doctor will also discuss any other medications you may take and how to record these on your trial diary.

Visit 2 - Baseline Visit (Within 1 week of visit 1)

This visit will include the following:

- Complete the CANTAB assessments
- Complete the walking assessment **(Newcastle participants only)**
- Have an MRI scan (if applicable)
- Have a blood pressure and pulse check
- Optional – have the additional blood samples taken for storing in the biobank
- Complete the trial questionnaires (the questionnaires will take around just over an hour) including Clinical Global Impression of Change assessment
- Be given your trial medication (placebo or Obeticholic Acid)
- Check if you are taking any new medications since the last visit
- Check if you are having any new symptoms
- Be given a patient diary and trial safety card

Visit 3 – Interim visit (Around 2 weeks after visit 2)

This visit will include the following:

- Have a blood pressure and pulse check
- Provide a blood sample to check how you are reacting to the trial medication – someone from either the research team or your care team will contact you if there are any concerns from these results
- Ask if you have started taking any new medications
- Check if you are having any side-effects from your trial medication
- The trial team will go through your trial diary to check how many tablets you have taken, any side-effects you have had and any other medications you are taking.

Visit 4 – Interim Visit (Around 4 weeks after visit 2)

This visit will include the following:

- Have a blood pressure and pulse check

- Take a blood sample to check how you are reacting to the trial medication – some from either the research team or your care team will contact you if there are any concerns from these results
- The trial team will go through your trial diary to check how many tablets you have taken, any side-effects you have had and any other medications you are taking.

Visit 5 - Telephone call (Around 8 weeks after visit 2)

This visit will be completed over the phone and the trial team will ask to go through your trial diary with you to check how many tablets you have taken, any side-effects you have had and any other medications you are taking.

Visit 6 – Interim Visit (Around 12 weeks after visit 2)

This visit will include the following:

- Have an ECG, blood pressure and pulse check
- Provide a blood sample to check how you are reacting to the trial medication – some from either the research team or your care team will contact you if there are any concerns from these results
- Optional – have the additional blood samples taken for storing in the biobank
- Complete the trial questionnaires (the questionnaires will take around just over an hour)
- You will be prescribed some more trial medication
- The trial team will go through your trial diary to check how many tablets you have taken, any side effects you have had and any other medications you are taking.

Visit 7 - Telephone call (Around 16 weeks after visit 2) and
Visit 8 - Telephone call (Around 20 weeks after visit 2)

These visits will be completed over the phone and the trial team will ask to go through your trial diary with you to check how many tablets you have taken, any side effects you have had and any other medications you are taking.

Visit 9 - End of trial medication visit (Around 26 weeks after visit 2)

This visit will include the following:

- Complete the second round of CANTAB assessments
- Complete the walking assessment **(Newcastle participants only)**
- A second MRI scan (if applicable)
- Have an ECG, blood pressure, pulse check
- Optional – have the additional blood samples taken for storing in the biobank
- Clinical examination
- Blood samples
- Complete the following
    - MDS UPDRS
    - Verbal fluency
    - MOCA
    - Clinical global impression of change
- Trial questionnaires
- Have the Axivity activity monitor attached for a second round of 7 day monitoring

- The trial team will go through your trial diary to check how many tablets you have taken, any side effects you have had and any other medications you are taking.

You will not be prescribed any more trial medication at this visit.

Visit 10 - Final visit (Around 30 weeks after visit 2)

This visit will include the following:

- Have a blood pressure and pulse check
- Blood samples
- You will also be asked if you have had any side effects from taking the tablets.

Further information

Expenses

We will reimburse any reasonable travel costs for you attending your trial visits. Please make sure you keep receipts to give to the trial team to arrange payment.

What are the possible benefits of taking part?

We cannot promise the trial will help you directly. We hope the information we get from this trial will help researchers to decide whether a larger clinical trial should be looked into to help to improve the treatment for PwP who also experience cognitive symptoms.

By being part of this trial you will also be more closely monitored and have follow up visits and calls which would not happen as part of your normal care.

What are the possible risks of taking part?

We want you to be safe in the trial at all times, but all medical treatments carry some risk. Obeticholic acid is currently licenced and use by the NHS in some patients diagnosed with Primary Biliary Cholangitis (PBC) in smaller doses. This is the first time it will have been used for patients with Parkinson's at this strength.

Some of the more common side effects that have been reported in PBC patients, are things like:

- Pruritus (itchy skin)
- Abdominal pain and discomfort
- Arthralgia (joint pain)
- Constipation
- Dizziness
- Fatigue
- Fever

- Oropharyngeal pain (pain at the back of throat)
- Palpitations (your heart might feel like it's pounding, fluttering or beating irregularly for few seconds or minutes at a time)
- Peripheral oedema (swelling in feet, ankles, legs, and/or hands)

To closely monitor how you are doing during your participation in the trial, we will need to do the following:

The trial team will check you at each trial visit to see if you have experienced any side effects, and it is very important that you tell the trial doctor or nurse about any side effects or other medical concerns that you have. Many adverse reactions go away soon after you stop your medication. In some cases, adverse reactions can become serious, long lasting, or may never go away; they may require hospitalisation and even, but rarely, lead to death.

We will need to take blood samples from you. Taking blood samples may cause some discomfort and minor pain, and some patients occasionally feel faint during or after the procedure. Sometimes patients will have some bruising where the blood has been taken. Trained members of staff will perform these procedures and every effort will be made to prevent these problems.
If you consent to the MRI scans you will have one at the start of the trial (baseline visit) and another after the end of your trial treatment (around 6 months later). There are no known risks with an MRI scan itself and they are not painful. The only discomfort some people feel is claustrophobia (fear of enclosed spaces) and the noise of the machine while in the scanner. You'll be given earplugs or headphones to wear and a button to hold onto while inside, should you wish to come out of the scanner before it finishes. If you are unable to have the MRI scans, or do not consent to them, you can still participate in the trial.

What happens at the end of the trial?

At around 26 weeks into the trial, you will stop taking the trial medication. After this we are unable to offer you any more medication as part of the trial as Obeticholic Acid is currently not licensed for use in Parkinson's. We hope, however, should this show promise, that we could take this forwards in to a larger trial in Parkinson's in the future, where participants from the current study would be invited. You will have one more visit at 30 weeks and then after this you will return to normal NHS care.

What if new information becomes available?

Sometimes during the course of a trial, new information becomes available about the drug being tested. If this happens, your trial doctor will tell you about it and discuss with you whether you want to continue in the trial. If you decide to withdraw, the trial doctor will make arrangements for your usual routine care to continue. On receiving new information, the trial doctor might consider it to be in your best interests to withdraw you

from the trial. He/she will explain the reasons and arrange for your usual routine care to continue.

What will happen if I do not want to carry on with the trial?

You can withdraw from the trial at any time without giving a reason. A decision not to take part at any stage will not affect the care you receive from your clinical team. If you withdraw from the trial, we will keep the information and samples that we have already obtained from you up to the point of withdrawal, but we will not collect any further information about you.

If you withdraw your consent, the trial team will contact you around 4 weeks after you have stopped your trial medication to check if you have experienced any problems.

Alternatively, you may choose to discontinue taking trial medication, but continue to attend trial visits. This information is still very useful to the researchers.

What if there is a problem?

If you have a concern about any aspect of your participation this trial, you can speak to the trial doctor or a member of the trial research team who will do their best to answer your questions. Further contact details are included at the end of this information sheet.

If you prefer to raise your concerns with someone not involved in your care, you can contact the Patient Advise and Liaison Service (PALS). This service is confidential and can be contacted on Freephone: SITE TO LOCALISE

Alternatively, if you wish to make a formal complaint you can contact the Patient Relations Department through any of the details below:

Telephone:	SITE TO LOCALISE
Email:	SITE TO LOCALISE
Address:	SITE TO LOCALISE

In the unlikely event that you are harmed during this research due to someone's negligence (they were careless), then you may have grounds for a legal action for compensation against Newcastle upon Tyne Hospitals NHS Foundation Trust (the trial Sponsor), but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). NHS Indemnity does not offer no-fault compensation (i.e. for harm that is not anyone's fault). Neither the Sponsor (The Newcastle upon Tyne Hospitals NHS Foundation Trust) who has undertaken to manage the trial, nor the management of the hospital/research centre you are attending for your routine treatment, is able to agree in advance to pay compensation for non-negligent harm.

Will my taking part be kept confidential?

Trial Funder – Intercept Pharmaceuticals

This trial is funded by a company called Intercept Pharmaceuticals, who make the Obeticholic Acid drug. Intercept Pharmaceuticals are based outside of the UK in the United States. If you take part in the OACS-3 trial, your data may be sent to Intercept Pharmaceuticals or third parties to process on Intercept Pharmaceuticals' behalf. This means that your data could be sent outside of the UK, including being sent to the United States. Data sent to Intercept Pharmaceuticals will be psuedoanonymised (you will be identified by a unique trial identification number and they will not know your name). Data sent to the United States will be sent in accordance to the Privacy Shield or equivalent. Intercept Pharmaceuticals may use your pseudonymised data for any research, regulatory or commercial purpose or to comply with Applicable Laws.

To find out more about research and general use of patient information please refer to the Health Research Authority Website https://www.hra.nhs.uk/information-about-patients/. You can also ask someone in the research team if you do not have online access.

Your trial information

All of the information collected in the trial will be entered on computers that are kept secure and password protected. The trial team at your hospital will have access to your information during the trial to contact you for your telephone call visits as well as to organise trial visits.

All personal details about you will be kept confidential and in accordance with the General Data Protection Regulation (GDPR) and will be stored in a secure place. Some parts of your medical records will be looked at by the researchers, authorised person from the responsible NHS organisation and representatives of regulatory authorities to make sure we carry out the trial properly.

As Newcastle upon Tyne Hospitals NHS Foundation Trust are the Sponsor for this trial, they will act as the data controller for this trial. This means that they are responsible for looking after your information. In their role as data controller, they must store it safely and check it is used in an appropriate way.

Intercept Pharmaceuticals (the trial funder) will also act as a Data Controller for OACS-3. They will receive pseudonymised data from Newcastle University (who are running the trial) which is generated by the trial.
This includes:

- Using data in relation to reviewing and processing safety data.
- Using the data to submit to regulatory authorities
- Using data in relation to the operational activities of Intercept Pharmaceuticals.

Intercept Pharmaceuticals may then transfer the pseudonymised data to third parties to process the data on their behalf.

OACS-3 is managed on behalf of the Sponsor by the Newcastle Clinical Trials Unit based at Newcastle University, who will act as a data processor for OACS-3. As a data processor, the Newcastle Clinical Trials Unit are responsible for processing data on behalf of a controller.

To ensure that our research is reliable and accurate we must manage your information in specific ways. This will limit your rights to access and change your information. We will keep any existing information about you up until the point of withdrawal from the trial. To safeguard your rights, we will use as little personal-identifiable information as possible in the information that is stored up to the point of withdrawal. In the rare event that you lose capacity during the trial, the data collected up to that point will be retained.

You can find out more about how we use your information by sending an email to the trial Sponsor Data Protection Officer: nuth.dpo@nhs.net

If you experience any serious adverse reactions or become pregnant while on the trial, we will send this information to the trial funder as they require this information as part of their record keeping on the trial drug, we have specific forms to send this information, and only your unique trial identification number will be used.

Trial Archiving

We must archive all trial information for at least 25 years after the trial ends. This allows any potential queries about the way we ran the trial to be resolved once it is over. To protect your confidentiality, all information will be archived securely. Your name and contact details will not be stored outside of your hospital(s). Any trial data held by the trial team at Newcastle University will be pseudonymised.

Informing your GP

Your GP and care team will be informed that you are taking part in this trial, but they will not know which treatment you are taking. They will also be given a copy of this information sheet.

What will happen to the results of the research trial?

The results will be published in medical journals and presented in meetings to other doctors, nurses, researchers and patients.

All trial data that is published will be anonymous. Your identity will always be protected.

Fully anonymised data may be made available to other researchers to help inform other research.

If you would like to see the results of this trial, we will make them available once they are published.

Who is organising and funding the research?

The central trial doctor (also known as the 'Chief Investigator') is Professor Dave Jones, who is a Consultant Physician who specialises in liver disease and research. He is based in Newcastle upon Tyne. The local trial doctor (also known as the 'Principal Investigator') is SITE TO LOCALISE, a consultant Physician who specialises in Parkinson's disease and research.

The trial Sponsor is the Newcastle upon Tyne Hospitals NHS Foundation Trust. OACS-3 is managed by the Newcastle Clinical Trials Unit, Newcastle University on behalf of the sponsor.

The trial funder for OACS-3 is called Intercept Pharmaceuticals.

Who has reviewed the trial?

The funder reviewed the trial plan as part of the application for funding. All research in the NHS is also looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This trial has been reviewed and given favourable opinion by London – Hampstead Research Ethics Committee.

Local Contact Details

If you are interested in this trial or would like more information, please contact the Investigator on XXX or Research Nurse/Team on XXX.

Notes

Please use this page to make any notes you would like to ask the trial team/trial doctor.

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