**To be printed on trust headed paper**

**TB-DILI Trial – Latent TB Cohort Trial**

**Participant Information Sheet**

Final V1.1 14 Jul 2022

IRAS Project ID:1005097

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| 1. **You are invited to take part in our research trial** |
| * The purpose of this information sheet is to help you understand why the research is being carried out and what it will involve for you if you decide to take part * Please take time to read this information carefully and ask us if there is anything that is not clear to you or you would like more information * It is entirely your decision whether to take part in this trial. If you agree to take part, you are free to withdraw at any time without giving a reason. If you choose not to take part, your care will not be affected |
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| 1. **A summary and purpose of the trial** |
| In the UK, Latent tuberculosis infection (LTBI) is routinely treated with a combination of three medicines, this is referred to as 3-drug anti latent TB therapy. Most patients can successfully complete their treatment course with no complications. Unfortunately, in some cases, the medicines can begin to cause damage to the liver, this is called drug-induced liver injury (DILI). To protect the liver and encourage it to recover the TB treatment is stopped.  Once the liver has recovered doctors must decide how or whether to restart anti-TB drugs. The aim of the latent TB cohort trial is to determine the frequency of drug induced liver injury (DILI) and the frequency of DILI recurrence in patients being treated for latent TB. The trial also aims to assess the impact of DILI on a patient’s quality-of-life. |
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| 1. **Why have I been invited to take part?** |
| You have been invited to take part in this trial as you were being treated for a latent TB infection and your treatment has been stopped due to suspected damage to your liver. |
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| 1. **Do I have to take part?** |
| It is up to you whether or not you take part in the trial. Your decision will not affect your access to care. We will talk to you about the trial and answer any questions you may have. |
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| 1. **What would taking part involve?** |
| If you decide to help with this research, you will be asked to sign a consent form. Once that form is completed the medical information relating to your liver injury and anti-latent TB treatment will be sent to one of the trial team liver specialists supporting the trial to confirm the diagnosis of DILI. They will have a maximum of 5 days to confirm whether or not the liver damage is related to your TB treatment.  After the DILI is confirmed as being related to your TB treatment, you will be asked to fill in a short questionnaire about your health and wellbeing that will take a few minutes to complete.  If the liver specialists do not find that your liver injury is related to your TB treatment based on a specified criteria for the TB-DILI cohort trial, then you will not be eligible to continue into the trial. Your care will not be affected, and you doctor will manage your care as they see clinically appropriate.  Your doctor will manage your care as usual as you recover from the DILI. Once your liver has recovered and you have completed the questionnaire again the treatment you will receive will be decided by your doctor.  Your doctor will continue to manage your care as usual in the NHS and provide information on your health to the trial team. This trial does not require you to attend any additional visits than you would normally attend for TB treatment.  The trial team will monitor your treatment and recovery for 12 months after you have been enrolled into the trial. During that time, the trial team may contact you by phone, e-mail or post to update you on the trial, remind you to complete the questionnaires or to collect data about how you have been feeling since your last contact with them. |
| 1. **What are the possible benefits of taking part?** |
| Taking part in the trial may not directly benefit you, but the information we collect from this trial will help us determine the frequency of drug induced liver injury (DILI) and the frequency of DILI recurrence in patients being treated for latent TB. The trial also aims to assess the impact of DILI on a patient’s quality-of-life. |
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| 1. **What are the possible disadvantages and risks of taking part?** |
| The latent TB DILI cohort trial will involve data collection only, and will not affect the treatment or care you receive in any way. We therefore do not expect there to be any additional risks or disadvantages to your taking part in the trial. |
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| 1. **What if there is a problem?** |
| If you have concerns or questions about any aspect of this trial, you should ask to speak to the local researchers. Their contact details are at the end of this information sheet. If any questions remain you can contact the trial coordinating centre:  Tel: 0115 xxxxxxxx Mon to Fri: 08:00 – 16:00  Email: [TB-DILI@nottingham.ac.uk](mailto:TB-DILI@nottingham.ac.uk)  If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure via your local Patient Advisory and Liaison Service (PALS) <insert Local PALS details>.  If you are harmed and this is due to someone’s negligence, then you have grounds for a legal action for compensation, but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you. |
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| 1. **What will happen if I don’t want to carry on with the trial?** |
| You are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw the information collected will not be erased and this information may still be used in the project analysis. |
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| 1. **How will information about me be used?** |
| Researchers at the Nottingham Clinical Trials Unit (part of the University of Nottingham) will need to use information from you, your medical records, and your TB care team for this research project. All information about you will be kept safe and secure.  This information will include your initials, NHS number, name and contact details.  The researchers will use this information to do the research or to check your records to make sure that the research is being done properly.  People who do not need to know who you are will not be able to see your name or contact details, your data will have a code number instead.  Once the trial has finished, some of the data will be kept so the results can be checked and you can be told what happened in the trial (unless you tell us you do not want to know). Reports will be written in a way so that no-one can work out that you took part in the trial. |
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| 1. **What are your choices about how your information is used?** |
| You can stop being part of the trial at any time, without giving a reason, but we will keep information about you that we already have. If you choose to stop taking part in the trial, we would like to continue collecting information about your health from central NHS records. If you do not want this to happen, tell us and we will stop.  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.  After 25 years your data collected during the trial will be disposed of securely. If you give us your permission, we may keep your contact details so we can get in touch if there is any relevant future research that you may be interested in taking part in. You will also have the option to take part in future research using your data saved from this trial. If you do not wish for your contact details to be kept for a copy of the trial results to be sent to you or to be contacted about future research, these will also be disposed of securely at the end of the trial. |
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| 1. **Where can you find about more about how your information is used?** |
| You can find out more about how we use your information:   * at [**www.hra.nhs.uk/information-about-patients/**](https://www.hra.nhs.uk/information-about-patients/) and  [**www.hra.nhs.uk/patientdataandresearch**](http://www.hra.nhs.uk/patientdataandresearch) * at <sponsor privacy notice website address> * by asking one of the research team * by sending an email to [TB-DILI@nottingham.ac.uk](mailto:TB-DILI@nottingham.ac.uk) * by calling the Nottingham Clinical Trials Unit on <trial phone number> |
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| 1. **Who is organising and funding this trial? How has it been approved?** |
| The trial is being organised by the Nottingham University Hospitals NHS Trust (the Sponsor) and coordinated by the Nottingham Clinical Trials Unit (NCTU). The funding for the trial is provided by the National Institute for Health Research (NIHR). All research in the NHS is 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 **North East – Tyne & Wear South** Research Ethics Committee.  Patients who have previously been treated for TB have helped us plan and design this trial. Patients are also involved in the teams that oversee the running of the trial. |
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| 1. [**What if relevant new information becomes available?**](http://hra-decisiontools.org.uk/consent/content-sheet-support.html#ten) |
| Sometimes during a trial we get new information about treatment for a particular illness. If this happens during this trial your research doctor will tell you about this new information and discuss whether you should continue in the trial. If you decide not to carry on, your research doctor will make arrangements for your care to continue as normal. If you decide to continue in the trial, they may ask you to sign a new Informed Consent Form. |
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| 1. **What happens at the end of the trial?** |
| This trial should conclude 12 months after you have been enrolled into the trial. If you withdraw from the trial, we will need to keep and use the data collected up to your withdrawal. At the end of the trial the results will be published in scientific medical journals and presented at conferences. You will not be identified in any publication. We will send you a newsletter with a summary of the trial findings unless you ask us not to. |
| 1. **How to contact us** |
| Contact details of your local care team:   * <insert contact details here> |
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