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mulTiArm therapeutiC sTudy in pre-Icu patients admitted with Covid-19-Repurposed drugs (TACTIC-R)

PARTICIPANT INFORMATION SHEET & INFORMED CONSENT FORM

You are being invited to take part in a COVID-19 research trial. Please take the time to read the following information carefully and ask us if you have any questions.

MORE INFORMATION IS AVAILABLE AT www.tactictrial.net

1. What is the purpose of the trial?

COVID-19 is a disease affecting the lungs and is caused by a new coronavirus known as SARS-CoV2. The purpose of this trial is to identify the best way to treat patients infected with COVID-19 by comparing different treatments which act on the immune system. The reason for this is because in severe COVID-19 infection, there is an "over-reaction" of the immune system which involves the whole body. This has led to interest in drugs that control or "modulate" the immune system as potential treatments.

2. What treatments are investigated?

This study is investigating the drugs Baricitinib (commonly used to treat rheumatological conditions), Ravulizumab (commonly used to treat a condition called paroxysmal nocturnal haemoglobinuria) to standard care that you receive in hospital if you didn't join the study. Both trial drugs work to "calm down" the immune system.

3. Which treatment will I receive?

The treatment you will receive will be allocated to you at random (like rolling a dice). This means you will receive either Baricitinib daily until discharge from hospital and for a maximum of 14 days, OR Ravulizumab as a single injection, OR the standard of care you would normally receive. As the study progresses, additional drug treatments may be added or removed, depending on the latest scientific evidence. We may also take samples of your blood for routine clinical tests, and the option of an additional sample to look at your response to the infection.

4. What are the side effects of the drugs?

Baricitinib:

- Common (less than 10% of patients): upper respiratory tract infections (including colds), nausea, cold sores, shingles, skin rash, , sick stomach, urinary infection, pneumonia, high levels of liver enzymes.
- Uncommon (less than 1% of patients): weight gain, low levels of blood immune cells, blood clots, facial swelling, acne, increased risk of blood clots.

Ravulizumab:

- Very common (more than 10% of patients): upper respiratory tract infections, headache, common cold.
- Common (less than 10% of patients): meningococcal infection, dizziness, nausea, vomiting, skin rash, itching, back, joint and muscle pain, muscle spasms, fatigue, flu-like illness, fever, chills.

5. Why have I been invited?

You have been invited to participate in this trial because you are or suspected to be COVID-19 positive and are considered to be at risk of developing severe symptoms. We also believe that you may benefit from receiving baricitinib or ravulizumab.

6. Do I have to take part?

Joining the study is voluntary. Your care will not be affected by your decision whether you take part.

7. What are the possible benefits?

We are not yet sure if the treatments will have any benefit, but this study will help to identify treatments for future patients.

8. What are the possible risks of being in the study?

Apart from the known side effects of these treatments (see above), you may feel a slight discomfort at the injection site when the ravulizumab is given – this will be monitored by the trial team. Ravulizumab can increase the risk of developing meningitis. Therefore if you were randomized to ravulizumab, you will need to take a course of antibiotics until told to stop by a doctor, and be vaccinated against meningitis. These antibiotics should be taken until vaccination and for at least 2 weeks after the vaccination. If you do not wish to, or cannot be vaccinated, the antibiotics will need to continue for 8 months.

9. What happens when the trial stops?

Once the trial has ended you will be referred back to regular treatments. Pending the results of the trial, treatment guidelines may change. If you or your doctor wants to stop the study treatment, you can stop taking further treatment at any time.

10. Can I stop the study treatment or my participation early?

If you want to stop the study treatment before the course has been completed, then you are free to do so. If you decide that you do not wish any more information to be collected about you, feel free to say so (but de-identified information and samples that have been collected up to that point will continue to be analysed by the research team).

11. Expenses & Payment?

You will not receive any payment for participating in this trial and we are unable to reimburse any expenses incurred by your participation in this trial.

12. What if there is a problem?

If you have any concerns about any aspect of this trial, you should speak to your trial doctor who will do their best to answer your questions. If you wish to complain or have any concerns about any aspect trial, you can do this through the NHS complaints procedure. In the first instance it may be helpful to contact the Patient Advice and Liaison Service (PALS email and phone number) at your hospital.

13. Will my personal information be kept confidential?

All information about you and your health will be kept private. The only people allowed to look at your personal information will be the doctors who are running the study, the staff at the study coordinating centre, and the regulatory authorities who check that the study is being carried out correctly. A privacy notice and a more detailed patient information sheet is on the study website.

14. What will happen to the results of the trial?

The results of the trial will be anonymous and you will not be able to be identified from any of the data produced. When the results of this trial are available, they may be published in peer reviewed medical journals and used for medical presentations and conferences. If you would like to obtain a copy of the published results, please contact your trial doctor directly who will be able to arrange this for you.

15. Who is funding and sponsoring the trial?

The trial is being funded by Eli Lilly and Company UK Ltd and Alexion Pharma UK Ltd., and is sponsored by Cambridge University Hospitals NHS Foundation Trust.

16. Who has reviewed this trial?

This trial has been reviewed and given favourable opinion by an independent Research Ethics Committee (name of REC here), to protect your interests. The Medicines and Healthcare Products Regulatory Agency (MHRA) who are responsible for regulating medicines in the UK have also reviewed this trial.

Further information and contact details

If you have any questions or require any further information about the trial, please feel free to contact:

*Study Doctor name: telephone: **********email: *********************
*Study nurse/coordinator name: telephone: ********** email: *********************

In the event of an emergency please contact:

List 24 hour emergency contact detail here – this must match the information provided on the patient ID card and will be used to test the out of hours procedure for the trial.

NHS
Cambridge University Hospitals
NHS Foundation Trust

INFORMED CONSENT FORM

Trial Title: mulTiArm therapeutiC sTudy in pre-Icu patients admitted with Covid-19 - Repurposed drugs (TACTIC-R)

Principal Investigator: _____ **Participant Number:** _____

1	I have read and understood the Short Participant Information Sheet version 1.0 dated 20/05/2020 for the above trial and I confirm that the trial procedures and information have been explained to me. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided.
2	I understand that my participation in this trial is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected.
3	I understand that personal information about me will be collected and used in accordance with this information sheet. This information will be kept in the strictest confidence and none of my personal data will be published.
4	I understand that my GP will be informed of my participation in this trial and sent details of the TACTIC-R trial.
5	I understand that the information held and maintained by the central UK NHS bodies may be used to help contact me or provide information about my health status as part of this trial.
6	I understand that my personal data might be transferred between the trial team at different trial sites in relation to my participation in this trial. I understand that any personal data will be sent using (secure/encrypted mail servers etc).
7	I understand that I may not receive the results from COVID-19 test/s I take as part of this trial.
8	I understand that the doctors in charge of this trial may close the trial, or stop my participation in it at any time without my consent.
9	I agree to provide blood samples for research related to this trial, which may be stored for up to 5 years. I understand that my samples may be transferred to a central location for future analysis.
10	I agree that DNA will be isolated from my donated blood sample and analysed through the use of advanced laboratory techniques.

I agree to participate in this trial:

_____ _____ _____

Name of patient Signature Date

_____ _____ _____

Name of person taking consent Signature Date

Time of Consent (24hr clock) _____:_____

1 copy for the patient, 1 copy for the trial team, 1 copy to be retained in the hospital notes.

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OPTIONAL

11	I am happy to be contacted in the future about further trials or extensions to this trial.		
12	I am happy for my information to be exchanged with other study teams where I have also been involved in a COVID19 biomarker study		

FOR WOMEN OF CHILDBEARING POTENTIAL ONLY

		YES	NO
13	If I become pregnant during, or in the 8 months after receiving the trial drugs, I agree to information being collected about me, my pregnancy and my baby.		
14	I understand that sections of my medical notes or information related directly to my pregnancy may be looked at by responsible individuals from the sponsor, regulatory authorities and research personnel where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.		
15	I agree to give my pregnancy information voluntarily and understand that I am free to withdraw at any time without giving a reason and without my medical care or legal rights being affected. I understand that all data collected up to the withdrawal of consent will be kept confidential.		

I agree to participate in this trial:

_____ _____ _____

Name of patient Signature Date

_____ _____ _____

Name of person taking consent Signature Date

Time of Consent (24hr clock) _____:_____

1 copy for the patient, 1 copy for the trial team, 1 copy to be retained in the hospital notes.

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Principal Investigator: _____ **Participant Number: _____**

If participant is not able to read the text and/or sign for themselves but has capacity to give consent

I witnessed accurate reading of the consent form to the potential participant, who could ask any questions and got satisfactory replies. I confirm that they gave their consent freely.

…… …… ……../……../……..…
PRINTED name of witness Signature Signature Date

…… …… ……../……../……
PRINTED name of person taking consent Signature Signature Date

If participant temporarily lacks capacity to give consent due to the severity of their medical condition (e.g. acute respiratory failure or need for immediate ventilation):

I have read the information (or had it read to me) and had an opportunity to ask questions. I understand that the patient will be asked to confirm their consent as soon as they have the capacity to do so and that if they wish, they will be able to withdraw from the study without it affecting their medical care. I believe that if they were able to, the patient would wish to take part in this study.

…… …… ……../……../……
PRINTED name of Legal Representative Signature Signature Date

…… Relationship to participant

…… …… ……../……../……
PRINTED name of person taking consent Signature Signature Date