

ADD LOGOS

TO BE PRINTED ON HEADED PAPER



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

Patient Information Leaflet and Informed consent form Endothelial cell collection (optional)

This is an additional information sheet to the one you have already been given about the clinical trial called TACTIC-R. This sheet provides information for the optional procedure which is endothelial cell collection. It is not a compulsory part of the TACTIC-R trial, and you may choose to take part in the trial without taking part in the optional procedure. If you decide to undergo this procedure you are free to change your mind and leave at any time without giving your reasons. Your current and future care will not be affected in any way.

What are endothelial cells?

Endothelial cells are a thin layer of cells that line the inside of every blood vessel in your body. The main job of endothelial cells is to act as a barrier between the blood and the blood vessels, but they also participate in a number of cardiovascular processes such as the formation of new blood vessels, clotting of the blood, regulation of blood vessel size, and inflammation.

What is the purpose of this procedure?

In order to better understand what processes the endothelial cells of COVID-19 patients are undergoing as part of disease progression, a small number of endothelial cells will be collected from some patients and studied.

What does this procedure involve?

We will insert a small plastic tube (drip or cannula) into a vein at your elbow. We will use this tube to take routine clinical blood samples and any research samples you have agreed to previously. To collect the endothelial cells, we will place a very thin flexible wire, which is often used clinically to help insert longer cannulae, through the tube into the vein. Some endothelial cells on the inner wall of your blood vessels will stick to this wire. The wire is then withdrawn and the tip of the wire saved so that the endothelial cells stuck to it can be collected and studied. This will take approximately 1 minute, and will be performed at the start of the study, again on day 14 (or discharge), and if you attend in person for any follow up visits. You do not have to agree to have a sample taken at each of these time points.

How should you prepare for the procedure?

There is nothing you need to do to prepare for this procedure.

Are there any risks?

You may experience some minor discomfort and bruising at the site of cannulation. As with any invasive procedure, there is a very small risk of infection. However, cannulation will be performed by a medical professional to minimize all risks.

What will happen to my samples?

We will undertake the same type of analyses as we will on blood samples – full details are provided in the main patient information sheet (www.tactictrial.net)

What happens to the results?

The results of this procedure will be reviewed by the study research team and used in COVID-19 clinical research to help us understand how COVID-19 affects patients, and ultimately to develop better standards of care.

Consent

	Initials
1. I have thoroughly read the Patient Information Leaflet: Endothelial cell collection (Version 1.0, dated 20 May 2020 and I confirm that the study procedures and information have been explained to me.	
2. I confirm that I have had the opportunity to ask any questions and that I am satisfied with the answers.	
3. I consent to take part in this optional procedure.	

Name of participant
(print)

Name of participant
(signature)

Date of signature
(DD/MMM/YYYY)

Name of person taking consent
(print)

Name of person taking consent
(signature)

Date of signature
(DD/MMM/YYYY)