

ADD LOGOS

TO BE PRINTED ON HEADED PAPER

**mulTi-Arm Therapeutic study in pre-ICu patients admitted with Covid-19 –
Experimental drugs
and mechanisms (TACTIC-E)**

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 E. This sheet provides information for the optional procedure which is endothelial cell collection. It is not a compulsory part of the TACTIC E 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 generation 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 cells will be collected from some patients and analysed.

What does this procedure involve?

We will insert a small plastic tube (drip or cannula) into a vein at your elbow. We will take routine clinical blood samples through this, and any research samples you have agreed to have taken. Following this we will place a very thin flexible guide wire, which is often used to help insert longer cannulae through the tube into the vein and then withdrawn it. Some endothelial cells on the inner wall of your blood vessels will stick to this wire. Normally, the wire is discarded after the cannula is in place. For this procedure, the tip of the wire will instead be saved and the endothelial cells that are stuck to it will be collected and analysed.

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?

This is a standard procedure frequently performed in routine clinical care. 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 better 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 27 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
)

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.