

Participant Information Sheet

1. TITLE OF RESEARCH PROJECT

Pulmonary Function in Divers following SARS-CoV-2 Infection.

Name of Researchers:

- Dr Ed Shattock, Dr Doug Watts
- We are both hyperbaric physicians working at DDRC Healthcare in Plymouth, interested in diving related disease and how it might impact the UK and worldwide diving population.

What is the purpose of the study?

SCUBA diving is an extremely popular sport in the UK with 350,000 people participating in the sport in 2015. It is also a relatively safe sport as shown by the BSAC incident report 2018, however there are risks involved, including decompression sickness, arterial gas embolism and pulmonary barotrauma. At DDRC, one of our charitable aims is to improve diver safety and diving accident management and we do this by conducting diver medicals, running the National Diving Accident helpline and educating the UK diving population. We also conduct research to try and stay at the forefront of dive medicine and to enable us to offer UK divers the most up-to-date information available.

At the time of writing, over 10 million cases of COVID-19 infection have been confirmed worldwide, with 285,000 cases confirmed in the UK. Although the death rate is concerning, many more victims are predicted to recover from infection and currently there is little data on their post-infection recovery. One concern that has been noted is the potential for reduced lung function following recovery from COVID-19, even in those patients who may have had very mild or even no symptoms. Any reduction in lung function and exercise capacity is a concern for divers as it may impact on their fitness to dive in the future.

At DDRC we are in an almost unique position where we have routine lung function data for many occupational divers and some recreational divers from previous medicals and so can compare results from before and after COVID-19 infection to see if there is a significant difference. Results from this study would help to better inform SCUBA divers about a safe return to the water but also improve our understanding of this novel disease and help better manage survivors across the globe.

Why have I been invited?

You have been invited to take part in this study because you have shown interest in helping with the study. To take part you must have tested positive for coronavirus or had symptoms consistent with coronavirus and have had a medical with us at DDRC in the past 5 years.

Do I have to take part?

Taking part in the study is entirely voluntary. If you do decide to take part, you will be asked to complete a consent form on your visit to the centre where we explain what risks might be involved. You will be met by one of the research team who will explain the study to you in full and answer any questions you may have.

What will happen to me if I take part?

If you do decide to take part then you will be called by one of the researchers to discuss a visit to DDRC. Due to the coronavirus outbreak we must ensure that the risks of transmission are kept low so we will discuss any symptoms with you as well as the need to maintain social distancing and to keep an eye out for any COVID symptoms. You will then be invited to visit us at DDRC for testing. It will be very similar to a regular sports diver medical. You will be seen by one of the research team who will go through the consent form with you and then discuss your medical history and also examine you including listening to your heart and lungs. You will also have a heart tracing and undergo lung function testing and finally do an exercise test which involves step on and off a small box to a rhythm. Ideally this appointment will take place roughly 6 months after your coronavirus infection. We intend to repeat this appointment again 12 months after your initial infection to see if there has been any further change.

We will record your past medical history and examination findings on our healthcare system along with the results of lung function and exercise tests. This is password protected and only accessible to the healthcare team. The data will be kept as part of your DDRC healthcare record and can therefore be used in any medicals you have with us.

Expenses and payments

Although you will not be reimbursed for your time, the study will take the form of a Sport Diver Medical which you will not be charged for. The UKDMC have advised that all divers who have suffered from proven or presumed COVID must have a face-to-face medical prior to returning to the water. As this study is run by qualified Diving Doctors we will be happy to sign off your diving medical declaration free of charge, providing you fulfil the criteria to be fit to dive.

What are the advantages of taking part?

- You will have the opportunity to be involved in research which has the potential to benefit millions of survivors of COVID-19.
- You will be assessed by a qualified diving doctor who can sign you off as fit to dive at the end of the study, providing you fulfil the UKDMC criteria.

What are the possible disadvantages and risks of taking part?

- The exam requires a reasonable level of fitness to complete.
- If we find that you do not meet the criteria to be fit to dive, we will have to inform you of this and recommend that you do not dive until improved and reassessed by a diving doctor.

Will my taking part in the study be kept confidential?

As with all medicals at DDRC, the data collected during the study and your attendance at DDRC are strictly confidential. The researchers are trained to protect the confidentiality and anonymity of participants and their data at all times, although we may ask your permission to share information

with your GP if we find something relevant during your assessment. All data will be stored on the healthcare system at DDRC which accessible to only qualified health professionals.

During the study, authorised persons from the University of St Mark and St John may look at collected data to ensure the study is being carried out correctly. These persons will all have a duty of confidentiality to the research participant and will do their best to meet this duty.

Data which is collected during the study will be recorded in your patient file on the healthcare system at DDRC. As mentioned previously, this is only accessible to our qualified healthcare professionals, but will be kept in your record and can be used as part of future medical assessments should you choose to have them conducted with us at DDRC.

What will happen if I don't want to carry on with the study?

If you begin the study but later decide that you do not wish to take part then this is absolutely fine, simply inform one of the research team. You do not have to give any reason to want to leave the study. Unfortunately, as the data forms part of our clinical record it must be kept as part of your patient file but we will not use the data in the study itself without your consent. However, once the data collection process has been completed, we will collate and anonymise the data, at which point we will be unable to remove your information from the study.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to one of the researchers who will do their best to answer your questions, contact details are at the end of the information sheet.

If you have any questions about your rights as a research participant, or wish to make a complaint, you can contact the University Research Ethics Panel at ethicspanel@marjon.ac.uk

What will happen to the results of the research study?

Results of the study will hopefully be published in a peer-reviewed scientific journal if accepted. Any data published will be totally anonymous and you will also have the opportunity to read a draft copy prior to publishing. We may also present the results of the study at conferences, again with completely anonymised data.

Thank you for taking the time to read the information sheet. If you decide to participate you will be given a copy of the information sheet to keep and your consent will be sought.

Contact details:

ftd@ddrc.org – 01752 209999

DDRC Healthcare, Hyperbaric Medical Centre, Research Way, Plymouth Science Park, Plymouth, Devon, PL6 8BU.