

Vaccine efficacy research studies in people with kidney disease in the UK

Early data is emerging from around the world that COVID vaccination provides protection from severe infection. The results are consistent with the excellent efficacy reported from the clinical trials.

However, patients with kidney disease and weakened immune systems were excluded from the vaccine trials, so how well they work in these patients is unknown. This is an unfavourable situation given that these patients are also considered to be at greater risk of severe infection.

The Renal Association has convened a multi-disciplinary group to inform the kidney community on vaccine outcomes. This working group has been split into two main research areas:

1. Vaccine hesitancy
2. Vaccine efficacy

This rest of this report focuses on studies taking place to understand if the vaccines will be effective in patients with kidney disease.

Will COVID vaccines work in people with kidney disease?

To answer this, separate studies are required:

1. Laboratory studies which will detect immune responses in the blood.
2. Registry data on how the vaccine impacts on infection rates and outcomes (real world evidence).
3. Whether the laboratory tests correlate (predict) the real world evidence.

The UK renal registry will be reporting on the real world evidence but the laboratory based research studies will rely on researchers, patients and funders.

We are happy to report that many kidney centres across the UK are already undertaking such studies. Furthermore, with support from charities such as Kidney Research UK and the National Kidney Federation, together with academic funding bodies, these researchers are joining forces in order to

answer the most relevant questions as quickly as possible, whilst ensuring the highest quality of work.

A summary of the active studies is described below:

1. Study of vaccine responses in patients receiving in-centre haemodialysis

Supported by KRUK and NKF

Aiming to study 1200 haemodialysis patients

Centres recruiting: Birmingham, Cambridge, Glasgow, Imperial, Leicester, Newcastle, Oxford, South Tees

For more information about the study, please follow the link below: [New study will reveal how well Covid-19 vaccines protect dialysis patients - Kidney Research UK](#)

2. OCTAVE Study (Observational Study of T-cells, Antibodies and Vaccine Efficacy in SARS-CoV-2)

MRC supported study

Aiming to recruit 150 dialysis patients and 850 transplant patients

Lead kidney centre: Imperial

OCTAVE sites (Glasgow, Birmingham, Liverpool, Kings, Leeds, Oxford, Cambridge)

For more information about the study, please follow the link below: [University of Glasgow - Research - Coronavirus research - OCTAVE to study vaccine responses in patients with impaired immune systems](#)

3. Determining functional immunity after SARS-CoV-2 vaccination or natural infection in haemodialysis patients at high-risk of COVID-19

Supported by UK Research and Innovation

Aim: To recruit 100 patients requiring haemodialysis treatment and 100 controls to assess the function of antibodies generated following COVID 19 infection or vaccination to COVID 19 and the ability of immune cells to clear virus in the presence of antibody

Chief Investigator: Professor Lorraine Harper
Site: Birmingham

In addition to the above studies, many centres are undertaking local research studies, including patients with kidney disease not requiring renal replacement therapy and patients with glomerulonephritis. The aim of the Renal Association group is also to ensure the needs of all patient groups are met, and we will endeavour to provide evidence for groups not yet represented in the above studies.

We expect data to start emerging from the single centre studies imminently, with the first data from the KRUK/NKF supported study expected as early as May. We will aim to link all relevant publications onto the Renal Association and Kidney Care UK websites.

All studies will aim to adapt to changes in clinical need. The Renal Association working group will also support the translation into routine clinical care, of any evidence of best practice produced by these or other informative studies.