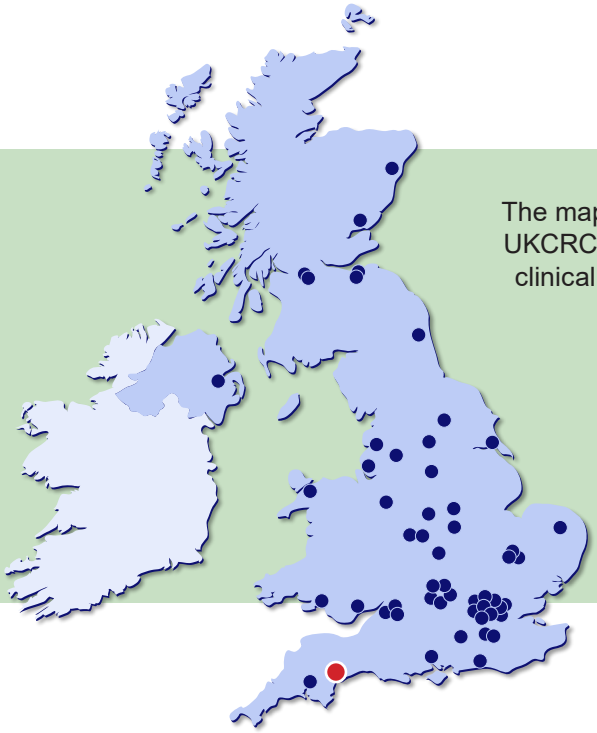
UKCRC Registered Clinical Trials Units

Exeter Clinical Trials Unit

The BRACE Trial

Exeter CTU rapidly sets up the UK-arm of the largest clinical trial in the world to investigate whether the BCG vaccine has protective effects against COVID-19.



The map shows all UKCRC registered clinical trials units

On the frontline of novel infectious disease outbreaks like COVID-19, healthcare professionals (HCP) are at high risk of illness – while absenteeism due to COVID-19 exacerbates the pressure on our healthcare system.

While COVID-19-specific vaccines are in development and being rolled out, it is imperative to find other ways to protect HCPs from COVID-19. The BRACE trial seeks to do just this, by investigating whether the safe, cheap and readily-available Bacille Calmette-Guerin (BCG) vaccine could protect against COVID-19 and other infections.

Previous research has shown the BCG vaccine, normally used to protect against tuberculosis, can elicit a prolonged non-specific boost to the immune system which may protect against other infectious diseases and may improve the effectiveness of other vaccines. The BCG vaccine has been given to people for 100 years and has a well-documented safety profile.

The BRACE trial is sponsored by the Murdoch Children's Research Institute (MCRI), Melbourne, Australia. This global trial aims to recruit 10,000 participants from 34 sites in five countries: the UK, Australia, Spain, the Netherlands and Brazil. Exeter CTU, University of Exeter, is at the

forefront of the UK arm of this important trial. With strong links in primary care and care home settings, Exeter CTU was well placed to launch recruitment of healthy volunteers working in frontline healthcare.

The trial was set up in the UK in June 2020 and the first participant was recruited in early October 2020 – a remarkable achievement for a multi-centre randomised, placebo-controlled clinical trial of an investigational medicinal product (CTIMP) with international sponsorship.

Participants are randomised 1:1 to receive the BCG vaccine or a saline placebo, and are blinded to their allocation. The primary outcomes are symptomatic COVID-19 and severe COVID-19 (defined by death, hospitalisation or non-hospitalised severe disease) in the six months following randomisation.

In the UK, 175 participants were randomised between October 2020 and January 2021 and will now be followed up for up to 12 months.

Participants submit data about their health weekly using a custom-built mobile app, they complete online surveys and attend clinics to donate blood samples at 3, 6, 9 and 12 months post-randomisation.

The trial management and data management teams at Exeter CTU are working closely with sites and participants to maintain high follow-up data completeness, as well as continuing to support other elements of this international trial.

The MCRI has received more than $10M AUD from the Bill & Melinda Gates Foundation and $1.5M AUD from the Minderoo Foundation to allow for its global expansion. The Peter Sowerby Foundation has contributed funding to support the Exeter trial site.

For more information visit:
University of Exeter and mcri.edu.au/BRACE

murdoch children's research institute

BRACE trial
BCG vaccination to reduce the impact of COVID-19 in healthcare workers

The Royal Children's Hospital Melbourne
THE UNIVERSITY OF MELBOURNE
TELETHON KIDS INSTITUTE
SAHMRI South Australian Health & Medical Research Institute
NCIRS National Centre for Immunisation Research and Surveillance
UMC Utrecht
UNIVERSITY OF EXETER
UFMS UNIVERSIDADE FEDERAL DE MATO GROSSO DO SUL
FIOCRUZ
FUNDAÇÃO DE MEDICINA TROPICAL DOUTOR HEITOR VIEIRA DOURADO FMT-HVD