Research UPH Activity at SFH

RECOVERY – Total recruited 85

Full Title – Randomised Evaluation of COVID-19 Therapy (RECOVERY)

Principle Investigator – Dr Mark Roberts

Sponsor – University of Oxford

Funder – UK Research and Innovation

Objectives

To test a range of potential treatments that have been suggested for COVID-19 to determine how effective they are in helping people recover from COVID-19, than the usual standard of hospital care which all patients will receive. The Trial is testing/has tested some of the following treatments:

- Lopinavir-Ritonavir (commonly used to treat HIV)
- Low-dose Dexamethasone (a type of steroid, which is used in a range of conditions typically to reduce inflammation) (Open to children only as of 08/06/2020)
- Hydroxychloroquine (related to an anti-malarial drug) – Now closed due to preliminary results showing no additional efficacy
- Azithromycin (a commonly used antibiotic)
- Tocilizumab (an anti-inflammatory treatment given by injection)
- ABO-compatible convalescent plasma (provided by NHS BT)

Data from the trial will be regularly reviewed so that any effective treatment can be identified quickly and made available to all patients.
Please see link below for some ground breaking findings about Dexamethasone impact on patient's serious ill from COVID-19
https://www.nihr.ac.uk/news/first-drug-to-reduce-mortality-in-hospitalised-patients-with-respiratory-complications-of-covid-19-found/25061
The Trial team will constantly review information on new drugs and include promising ones in the trial.

GENOMICC – Total recruited 25

Full Title – Genetics of susceptibility and mortality in critical care (GenOMICC)

Principle Investigator – Dr Pulak Paul

Sponsor – NHS Lothian, University of Edinburgh

Funder – Wellcome Trust

Objectives

To identify the specific genes that cause some people to be susceptible to specific infections and consequences of severe injury, in the hope that by identifying these genes it will help to use existing treatments better, and to design new treatments to help people survive critical illness.
To do this, DNA and cells from carefully selected patients will be compared with samples from healthy people.

ISARIC – Total recruited 301

Full Title – Clinical Characterisation Protocol for Severe Emerging Infection

Principle Investigator – Dr Mark Roberts

Sponsor – University of Oxford

Funder – Wellcome Trust

Objectives

To:

- Describe the clinical features of the illness or syndrome
- Describe, where appropriate, the response to treatment, including supportive care and novel therapeutics.
- Observe, where appropriate and feasible, pathogen replication, excretion and evolution, within the host, and identify determinants of severity and transmission using high-throughput sequencing of pathogen genomes obtained from respiratory tract, blood, urine, stool, CSF and other samples.
- Characterise, where appropriate and feasible, the host responses to infection and therapy over time, including innate and acquired immune responses, circulating levels of immune signalling molecules and gene expression profiling in peripheral blood.
- Identify host genetic variants associated with disease progression or severity
- Understand transmissibility and the probabilities of different clinical outcomes following exposure and infection

PRIEST – Total recruited 224

Full Title – The PRIEST Study: Pandemic Respiratory Infection Emergency System Triage

Principle Investigator – Dr Jill Woodhead

Sponsor – Sheffield Teaching Hospitals NHS Foundation Trust

Funders – DH R&D HTA Programme, NIHR Health Technology Assessment Programme

Objectives

To optimise the triage of people using the emergency care system (111 and 999 calls, ambulance conveyance, or hospital emergency department) with suspected respiratory infections during a pandemic and identify the most accurate triage method for predicting severe illness among patients attending the emergency department with suspected respiratory infection.
The findings will be reviewed weekly by an expert group, who will summarise emerging findings to, when appropriate, inform policy makers and practitioners during a pandemic/epidemic.

PAN-COVID – Total recruited 4

Full Title – Pregnancy and Neonatal Outcomes in COVID-19: A global registry of women with suspected or confirmed SARS-CoV-2 infection in pregnancy and their neonates, understanding natural history to guide treatment and prevention

Principle Investigator – Miss Rebecca Holmes

Sponsor – Imperial College of Science, Technology and Medicine

Funder – Medical Research Council, NIHR/MRC (UKRI) - COVID-19 Rapid Response Call

Objectives

To develop a global database detailing a number of outcomes, death of the baby or mother, stillbirth, miscarriage, pregnancy complications, gestational age at delivery, delivery method and testing the baby for SARS-CoV-2.

This is to understand the natural history of SARS-CoV-2 and COVID-19 and the impact on mothers and their babies to guide both treatment and prevention.

REMAP-CAP – Total recruited 1

Full Title – Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia

Principle Investigator – Dr Valli Ratnam

Sponsor – Intensive Care National Audit & Research Centre (ICNARC) Clinical Trials Unit

Funder – University Medical Centre Utrecht

Objectives

To generate evidence that can be applied during the pandemic to reduce mortality or reduce the length of ICU admission in critically ill patients with COVID-19 infection, by studying the following on an open-label basis:

- Antiviral therapy (no antiviral, lopinavir/ritonavir (Kaletra)
- Immune modulation (no modulator, interferon-beta, anakinra, sarilumab, tocilizumab)
- Convalescent plasma (plasma versus no plasma)
- Therapeutic anticoagulation (heparin versus standard local antithrombotic treatment).

Corticosteroid domain: Closed to recruitment 16/06/20 in the light of the results from the RECOVERY trial.

Psychological Impact of COVID-19 – Total recruited 438

Full Title – Psychological impact of COVID - 19 - pandemic and experience: An international survey.

Principle Investigator – Mrs Lynne Allsop

Sponsor – Southern Health NHS Foundation Trust

Funder – NIHR/MRC(UKRI) - COVID-19 Rapid Response Call

Objectives

To explore the psychological impact of the COVID-19 outbreak, and the resultant restrictions in terms of behavioural, emotional and social factors.
Questions will be asked of the data collected to see what factors may be supportive or more detrimental to wellbeing. The general public including health professionals and those with pre-existing mental health conditions will be invited to complete the survey. This will enable identification of vulnerable groups who may experience more extreme or differing impacts to the rest of the population.

The questionnaire will be repeated after six months to allow for the development of the epidemic and measure the impact of restrictions being in place for a longer time period.

SIREN – In set up

Full Title – SIREN - SARS-COV2 immunity and reinfection evaluation; The impact of detectable anti SARS-COV2 antibody on the incidence of COVID-19 in healthcare workers

Principle Investigator – Miss Elizabeth Gemmill

Sponsor – Public Health England

Funder – Public Health England

Objectives

To find out whether healthcare workers who have evidence of prior COVID-19, detected by positive antibody tests, compared to those who do not have evidence of infection (negative antibody tests) are protected from future episodes of infection, by recruiting healthcare workers to be followed for at least a year, and study their immune response to COVID-19.

This study will provide very important information which will help to understand the future impact of COVID-19 on the population.

Canine Coronavirus Detection – In set up

Full Title – Using medical-detection dogs to identify people with SARS-CoV-2. Phase I. Proof-of-concept studies.

Principle Investigator - Unassigned

Sponsor – London School of Hygiene & Tropical Medicine

Funder – London School of Hygiene & Tropical Medicine COVID response fund and UK Department of Health and Social Care

Objectives

To determine whether trained dogs could detect asymptomatic, pre-symptomatic and prodromal symptomatic coronavirus infections in adults aged 20-70 years old.
This will be done by asking all NHS staff who are due to be screened for SARS-CoV-2 to wear a face mask for 3 hours and a pair of nylon socks for 12 hours and complete a short data collection sheet.

Upon confirmation of positive or negative swabs, the samples will be divided into two study groups.

The overall study will be conducted in three phases.

- Phase 1, is a proof-of-principle study to demonstrate that trained dogs can identify asymptomatic, pre-symptomatic or prodromal symptomatic infections with SARS-CoV-2 with high precision, and is the focus of this protocol.
- Phase 2, is an assessment of the capability of trained dogs to detect people infected with SARS-CoV-2
- Phase 3 is deployment of trained dogs at UK ports of entry.