

Update on COVID-19 research in Suffolk and NE Essex – 19/02/2021

COVID-19 Research findings and updates:

The latest results from the **RECOVERY** trial showed that **Tocilizumab**, an anti-inflammatory rheumatoid arthritis treatment, reduces deaths in patients hospitalised with COVID-19, reduces the length of hospital admission, and the risk of patients requiring mechanical ventilation. Read more [here](#). The RECOVERY is the second NIHR-supported study to demonstrate the effectiveness of tocilizumab as a treatment for COVID-19 patients, after results from the **REMAP-CAP** study last month showed that [tocilizumab and a second similar drug called sarilumab](#) have a significant impact on survival and can reduce the relative risk of death for critically ill patients in intensive care.

Vaccine trials and other New COVID-19 studies:

[First Children's COVID-19 vaccine trial](#) is now open to assess the safety and immune response to the Oxford/AstraZeneca coronavirus vaccine in children and young adults aged 6-17.

[CoVLP- A Randomized, Observer-Blind, Placebo-Controlled, Phase 2/3 Study to Assess the Safety, Efficacy, and Immunogenicity of a Recombinant Coronavirus-Like Particle COVID-19 Vaccine in Adults 18 Years of Age or Older and Children and Adolescents 5-17 Years of Age](#). The study is still in a set up stage.

COVID Oximetry @home (CO@h): A rapid patient experience study. A healthcare service called 'COVID Oximetry @home' has been nationally rolled out by NHS England and NHS Improvement. Within this service, patients are given a pulse oximeter and asked to record their oxygen levels regularly, either digitally or using paper-based diaries. Patients are monitored and sent for further care if problems arise. The aim of this NIHR funded study is to explore the experiences and behaviours (i.e. engagement with 'COVID Oximetry @home') of patients and carers who have received the 'COVID Oximetry @home' service. This will help to find out if healthcare services that require patients to monitor at home are effective, affordable and suitable and practical for both patients and healthcare professionals.

Coronavirus (COVID-19) SPIKE-1 trial. A Randomised Phase II/III community based trial to assess use of camostat as potential virus-blocking treatment in improving COVID-19 outcomes. The aim of this trial is to determine if camostat can reduce the clinical progression of COVID-19, and therefore the need for hospital admission and supplemental oxygen. Patients who test positive for COVID-19 but who have mild disease, will be recruited through various settings which may include primary care 'COVID-19 hub' clinics, COVID-19 community-based testing centres or other clinical environments. Patients will be randomised into the treatment arm (camostat tablets for 14 days) or control arm (best supportive care). The study will start with a pilot phase which will involve 100 participants.

Other news of interest

[DNA test which can quickly identify pneumonia in patients with severe COVID-19](#) developed by group of researchers from Cambridge in collaboration with Public Health England, will aid faster treatment for patients.

[£18.5 million awarded to new research projects to understand and treat long COVID.](#) The NIHR and UK Research and Innovation (UKRI) have funded four new research studies to better understand and address the longer term effects of COVID-19 on physical and mental health.

The tables below give an overview of all COVID-19 research activity across Suffolk. Please note that this information is provided for reference only and not for external publication.

Primary Care Studies

	Study Title	Study aim	Study setting	Local status		Recruitment ¹
1.	Principle: Platform randomised trial of Interventions against Covid-19 with older people https://www.phctrials.ox.ac.uk/principle-trial	To test different medications to see whether this reduces the need for hospitalisation or will speed up recovery in older patients (65+ or 50-64 with a pre-existing condition) hydroxychloroquine – recruitment paused Azithromycin – recruitment started Other medications may be added to the trial at a later point.	Primary Care	Sites activated: Suffolk: The Peninsula Practice; The Two Rivers; Victoria Surgery The Christmas Maltings & Clements Practice Chesterfield Drive Haven Health Derby Road	NEE: Colchester Medical Practice Castle Gardens Medical Centre; Parsons Health Medical Centre; Shrub End Surgery; Wimpole Rd Surgery; Great Bentley Surgery Ambrose Group Ardleigh Colne Medical Practice West Mersea Rowhedge Riverside	58 across Suffolk & NEE practices Nationally: 4,137
2.	FLU-CATS: Evaluation and refinement of pandemic influenza community assessment tools	An observational study of pandemic influenza community assessment tools which is being amended to pick up COVID-19 patients	Primary care	Awaiting revised protocol for COVID-19		Not yet set up
3.	VIVALDI COVID-19 in care homes	An observational study to understand SARS-COV-2 infection immunity and its duration in care home staff and residents in the UK	Care Homes	3 care homes in Suffolk / NEE are signed up.		North Court Care Home: 26 Catchpole Court Care Home: 36 Kingfisher House Care Home: 50 Nationally: 5,502

¹ Data collected from national research database – figures may lag behind actual figures

4.	RECAP (REmote Covid Assessment in Primary Care).	This research aims to develop a score for GPs to use when assessing how badly a patient is affected with COVID, to use over the phone or by video.	GPs and practices	Being set up across UK and Eastern	No recruits showed yet
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Cross Sector Studies

	Study Title	Study aim	Study setting	Local status	Recruitment ²
1	Chloroquine prevention of coronavirus disease (COVID-19) in the healthcare setting; a randomised, placebo-controlled prophylaxis study (COPCOV) http://copcov.org/	The aim of the study is to determine if hydroxychloroquine prophylaxis prevents symptomatic COVID-19 infection in front-line health care workers.	Secondary Care but with the expectation that frontline workers across all health and social care sectors would be able to take part as participants	East Suffolk and North Essex NHS Foundation Trust selected to participate; WSH in set-up	MHRA approved study to restart Nationally recruited: 88
2.	CROWN CORONATION Chloroquine Repurposing to healthWorkers for Novel Coronavirus mitigation <i>Study being amended to look at other prophylactic treatments instead of chloroquine / hydroxychloroquine</i>	The aim of the study is to determine the effectiveness of chloroquine/hydroxychloroquine prophylaxis in preventing symptomatic COVID-19 in healthcare workers at risk of SARS-CoV-2 exposure.	Secondary Care but with the expectation that frontline workers across all health and social care sectors would be able to take part as participants	ESNFT expected to take part	Not yet set up
3.	Virus Watch	An observational study into understanding community incidence, symptom profiles, and transmission of COVID-19 in relation to population movement and behaviour.	All sectors expected to be involved in collection of serum samples for participating households in Part 2 of the study. Part 1 is managed centrally	Colchester Medical Practice Howard House Surgery Oakfield Surgery Stowhealth The Chesterfield Drive Practice	Colchester Medical Practice: 79 Howard House Surgery: 36 Leiston Surgery: 71 Oakfield Surgery: 22 Stowhealth: 84 The Chesterfield Drive Practice: 82 Nationally recruited: 46,423

² Data collected from national research database – figures may lag behind actual figures

4.	Multi-centre European study of MAJOR Infectious Disease Syndromes (MERMAIDS): Acute Respiratory Infections in Adults	An observational study aims to identify host and pathogen related determinants of severity of community acquired acute respiratory infections in adults.	This study will enrol participants in both primary care and secondary care.	Trusts invited for expression of interest	Not yet set up Nationally: 47
5.	Behavioural Activation in Social Isolation (BASIL-C19)	This study is part of the MODS (Multi-Morbidity in Older adults with Depression Study) programme, looking at whether a talking treatment called Behavioural Activation (BA) can help improve a person's physical and psychological functioning, for example self-care and mood. The study is asking 'can we prevent or ameliorate depression and loneliness in older people with long term conditions who are under enforced COVID-19 isolation?'	Looking for Trust sites; with potential cross-sector involvement with primary care	Trusts invited for expression of interest	Not yet set up
6.	Post-hospitalisation COVID-19 study: a national consortium to understand and improve long-term health outcomes (PHOSP-COVID)	The aim is to understand and improve long-term outcomes for survivors of hospitalisation with COVID-19. The PHOSP-COVID study is aligned to the clinical follow-up provided, but does not alter clinical care.	TBC	TBC	Not yet set up
7.	Psychological Impact of COVID-19 N.B. the study adopted on NIHR portfolio but not badged with urgent public health status	A survey to explore the psychological impact of COVID-19 outbreak and the resultant restrictions in terms of behavioural, emotional and social factors.	Advertised through social media via local Trusts and CCGs	Norfolk & Suffolk NHS foundation Trust (NSFT)	NSFT: 104
8.	Novavax COVID Vaccine study – A trial to evaluate SARS-CoV-2 Recombinant Nanoparticle vaccine	12-month placebo controlled trial to evaluate the safety and efficacy of the Novavax Vaccine in adults 18-84.	Study based at ESNEFT and supported by Primary Care team	ESNEFT; recruitment completed	ESNEFT: 168 Nationally: 15,203

Secondary Care Studies

	Study Title	Study aim	Study setting	Local status	Recruitment ³
1.	RECOVERY: Randomised Evaluation of COVID-19 Therapy	To test if existing or new drugs can help patients hospitalised with confirmed COVID-19; The UK New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) advised that several possible treatments should be evaluated, including: Lopinavir-Ritonavir (arm closed-shown no clinical benefit; read more here), Interferon β, corticosteroids⁴, and Remdesivir, Hydroxychloroquine (arm closed; read more here), Tocilizumab, Dexamethasone, convalescent plasma . Other treatments may soon emerge that require evaluation. The supply arrangements for each medicine for RECOVERY trial are described here .	Secondary care; (Paediatric and neonatal arm to be added soon)	Open sites: ESNEFT (Ipswich and Colchester) WSH	WSH: 147 Ipswich Hospital: 353 Nationally: 35,761
2	RECOVERY-RS (Respiratory support) https://warwick.ac.uk/fac/sci/med/research/ctu/trials/recovery-rs/	This study is aiming to determine if CPAP (continuous positive airway pressure) or HFNO (high flow nasal oxygen) is clinically effective compared to standard care (excluding CPAP or HFNO).	Secondary care	Open sites: Ipswich Hospital Colchester WSH	ESNEFT:9 Nationally: 1,111
3.	Re-MAP Cap: Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia https://www.remapcap.org/	The trial will look at a number of different treatment categories with an aim to determine the best clinically effective treatment for adult patients with CAP admitted to participating intensive care units with suspected or microbiological testing confirmed COVID-19 infection.	Secondary care/ICUs	All sites running RECOVERY study are invited to participate	ESNEFT:34 Nationally: 4,028
4.	CCP-UK Clinical Characterisation Protocol for Severe Emerging Infection' study/(ISARIC-4C)	An observational study collecting samples and data from confirmed COVID-19 patients	Secondary care	All acute Trusts in the Eastern region activated;	ESNEFT: 2426 WSH: 983 Nationally: 177,785

³ Data collected from national research database – figures may lag behind actual figures

⁴ Corticosteroids used in the trial are expected to be sourced by local pharmacy procurement team via their normal routes, all other medications for RECOVERY sourced centrally via PHE

5.	UKOSS: Pandemic Influenza in Pregnancy https://www.npeu.ox.ac.uk/ukoss/current-surveillance/covid-19-in-pregnancy	An observational study via the UK Obstetric Surveillance System to collect information on pregnant women admitted to hospital with confirmed COVID-19	Secondary care / Trusts with Maternity Units	Open sites: Colchester; Ipswich hospitals; WSH	No recruitment data showing
6.	GenOMICC Genetics of susceptibility and mortality in critical care	An observational study to identify the specific genes that cause some people to be susceptible to specific infections and consequences of severe injury.	Secondary care	Ipswich Hospital open WSH reviewing	Ipswich Hospital: 64 WSH:1 Nationally: 10,196
7.	Coronavirus infection in primary or secondary immunosuppressed children.	An observational study designed to allow families of immunosuppressed children and young people to self-record their experiences of COVID-19 and other viral respiratory illnesses during the COVID-19 epidemic.	Secondary care	Not open to new sites currently	Recruitment now complete Nationally recruited: 1,633
8.	PAN COVID : Pregnancy and Neonatal Outcomes in COVID-19 https://pan-covid.org/	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	Secondary care	Open sites: WSH ESNFT (Ipswich & Colchester)	ESNEFT: 38 West Suffolk:3 Nationally: 6,187
9.	Neonatal Complications of Coronavirus Disease (COVID-19) Study	This is a national surveillance programme using the standard British Paediatric Surveillance Unit (BPSU) approach. This study will run alongside and be cross-linked with the maternal surveillance study run through the United Kingdom Obstetric Surveillance System (UKOSS; CPMS: 14162), which is already in progress.	Secondary care	Open sites: WSH	There will be no consenting (no recruits) for this study as linked to another study

10.	TACTIC-R (Multiarm Therapeutic study in pre-ICU patients admitted with COVID-19 - Repurposed Drugs)	The TACTIC-R clinical trial is testing whether existing drugs, which are already used to treat other immune-related conditions, can prevent the development of severe symptoms in patients hospitalised with confirmed/strongly suspected COVID-19. This approach, known as repurposing, is a way of finding out whether existing therapies, which are likely to be readily available in hospitals, are effective in treating the disease.	Secondary care	Several sites in Eastern are being set up Opened sites: WSH	WSH: 21 Nationally recruited: 408
11.	SIREN : Sarscov2 Immunity & REinfection EvaluationN - The impact of detectable anti SARS-COV2 antibody on the incidence of COVID-19 in healthcare workers	An observational study which aims to find out whether healthcare workers who have evidence of prior COVID-19 infection, detected by antibody assays (positive antibody tests), compared to those who do not have evidence of infection (negative antibody tests) are protected from future episodes of infection. For SARS CoV2 infection it is not yet known if the detection of antibodies protects people from future infection. This study aims to provide this very important information, which will help to understand the future impact of COVID-19 on the population.	Secondary care	Currently is being set up in secondary care – all trusts expected to take part as part of Trust wide antibody screening processes Open sites: WSH ESNEFT	WSH: 484 ESNEFT: 350 Nationally recruited: 33,921
12	NHS CHECK : Health & Experiences of staff working at NHS Trusts and Nightingale Hospitals https://www.kcl.ac.uk/news/nhs-check-study-to-explore-the-effect-of-the-covid-19-pandemic-on-nhs-staff	Aims to establish a cohort of NHS-affiliated staff to investigate the short, medium and longer term psychosocial impact of the COVID-19 pandemic on staff performance and wellbeing. NHS staff will be invited to participate, to complete an online survey module and an intervention evaluation module	Secondary care	Open sites: ESNEFT	ESNEFT: 425 Nationally recruited: 25,694

13.	What's the STORY?	This Oxford Vaccine Group study is investigating the serological profile of children and young adults to assess how well the population is protected from vaccine preventable disease. This study will involve blood sampling from people aged from birth to 24 years of age to look at their antibody levels against important infectious diseases.	Secondary care	Opened at: West Suffolk Hospital	WSH: 18 Nationally: 2,160
14.	CLARITY ImpaCt of bioLogic therApy on saRs-cov-2 Infection and immuniTY	This study will provide an evidence base for safer prescribing of immunomodulator and biologic drugs in the COVID-19 era and inform public health policy regarding physical distancing measures, and future vaccination strategies. Although this study will define risk in IBD (Inflammatory Bowel Disease) patients, there are potentially important lessons to be learned for other patients across with other immune mediated diseases treated with similar therapies.	Secondary care	Open at ESNEFT	ESNEFT: 29 Nationally: 7,206

⁵Local update

A full list of all DHSC priority COVID-19 studies can be found at <https://www.nihr.ac.uk/covid-studies/>