

Update on COVID-19 research in Suffolk and NE Essex – 01/04/2021

COVID-19 Research findings and updates:

The [Virus Watch](#) further findings published on the [Virus Watch website](#) include information on changes in attitude to vaccine uptake. 86% of people who said they were hesitant or unlikely to agree to have a vaccine when interviewed in December 2020 have now had one or intend to have one (as of February 2021). The findings also show that those in "overcrowded households" had twice the risk of SARS-CoV-2 infection compared to "under-occupied" (e.g. more rooms than occupiers) households.

[RECOVERY trial](#)

Dexamethasone, an inexpensive and widely available steroid, has saved around 22,000 lives in the UK and an estimated one million worldwide since its discovery as an effective treatment by the RECOVERY trial. Read more [here](#). In a special [webinar](#) to mark the one-year anniversary of the trial, the public are invited to hear directly from those who made it happen. ['The RECOVERY Trial: one year on'](#) was also recently featured on BBC radio 4 Inside Health.

NIHR vaccine trial animation

The NIHR have created an animation which aims to help people understand why COVID-19 vaccine trials are still needed. A version with voiceover is in the pipeline too and we'll share that when it's ready, but [here is the visual version on YouTube](#), which can also be shared via social media.

Also [Watch NIHR's short animation to find out the five ways research has fought COVID-19](#). Thanks to more volunteers joining studies, the funding into dozens of Urgent Public Health research studies and the unique structure of the NIHR, more and faster results have been achieved.

New COVID-19 studies:

NEW! FALCON C-19 (Facilitating Accelerated CLinical evaluation Of Novel diagnostic tests for COVID-19)- a platform adaptive diagnostic study utilising a national network of expertise in the evaluation of diagnostic technology. This study will enable the evaluation of multiple assays in three priority areas: evaluation of the diagnostic accuracy of vitro diagnostic tests (IVDs) for active infection with SARS-CoV-2; evaluation of assays monitoring the immune response to SARS-CoV-2 infection and evaluation of the prognostic value of commercially available tests for predicting prognosis in patients with suspected or confirmed SARS-CoV-2 infection. The FALCON C-19 focuses only on secondary care settings and is now open at is **open at West Suffolk Hospital NHS Foundation Trust**. A separate study (RAPTOR) is being initiated to evaluate IVDs for COVID-19 diagnosis in community settings.

[PROTECT-V \(PROphylaxis for paTiEnts at risk of COVID-19 - infecTion for Vulnerable patients\)](#). Led by Cambridge University Hospitals, PROTECT-V is a multi-arm, multi-stage study testing prophylactic interventions in patients at particularly high risk of COVID-19, and seeks to identify treatments that may prevent disease or reduce the number of severe, life-threatening cases.

Patients receiving dialysis, kidney transplant recipients, and patients with vasculitis or other autoimmune kidney disease and glomerulonephritis will be eligible, and will be randomised 1:1 to niclosamide or placebo in the first instance. A second intervention will be added shortly. Approximately 1500 participants will be recruited per arm (IMP vs. placebo, and IMP efficacy will be assessed by the rate of confirmed symptomatic Covid-19 infection.

HEAL-COVID (HElping Alleviate the Longer-term consequences of COVID-19) – Further information is available on this NIHR funded study looking into preventing deaths after COVID patients leave hospital. Read more [here](#).

Other news of interest:

[The future of UK clinical research delivery](#) – the new DHSC Policy ‘**Saving and improving lives: the future of UK clinical research delivery**’ sets out the ambition to create a patient-centred, pro-innovation and data-enabled clinical research environment, which empowers everyone across the health service to participate in delivering research and enables people across the country to take part in research that is of relevance to them. The vision was created as part of the Recovery, Resilience and Growth Programme with input from UKRD as well as the NHS, academia, life sciences industry, medical research charities, HRA, MHRA, NIHR and patient representatives. The vision has five key themes that underpin the improvements that will be taken forward in the coming months and years. Read also [press release](#).

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	74 across Suffolk & NEE practices Nationally: 4,717
2.	FLU-CATS: Evaluation and refinement of pandemic	An observational study of pandemic influenza community	Primary care	Awaiting revised protocol for COVID-19		Not yet set up

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

	influenza community assessment tools	assessment tools which is being amended to pick up COVID-19 patients			
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
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

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</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

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

	<i>instead of chloroquine / hydroxychloroquine</i>				
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: 40 Leiston Surgery: 69 Oakfield Surgery: 22 Stowhealth: 84 The Chesterfield Drive Practice: 82 Nationally recruited: 55,852
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	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

	N.B. the study adopted on NIHR portfolio but not badged with urgent public health status				
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 (completed, benefits found read more here) convalescent plasma (closed to recruitment); REGN-COV2 monoclonal antibodies directed against coronavirus; aspirin, colchicine, baricitinib and dimethyl fumarate. 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: 169 Ipswich Hospital: 397 Nationally: 39,374
2	RECOVERY-RS (Respiratory support)	This study is aiming to determine if CPAP (continuous positive airway pressure) or HFNO (high flow nasal oxygen) is clinically	Secondary care	Open sites: Ipswich Hospital Colchester	ESNEFT:9 Nationally: 1,264

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

	https://warwick.ac.uk/fac/sci/med/research/ctu/trials/recovery-rs/	effective compared to standard care (excluding CPAP or HFNO).		WSH	
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:38 Nationally: 4,384
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: 3272 WSH: 1102 Nationally: 198,252
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: 71 WSH:1 Nationally: 11,960
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,	Secondary care	Open sites: WSH ESNFT (Ipswich & Colchester)	ESNEFT: 42 West Suffolk:5 Nationally: 7,282

		understanding natural history to guide treatment and prevention			
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: 24 Nationally recruited: 421
11.	SIREN: Sarscov2 Immunity & REinfection Evaluation - 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: 533 ESNEFT: 352 Nationally recruited: 42,901

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: 434 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: 72 Nationally: 2,595
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: 31 Nationally: 7,231
15.	<i>NEW!</i> FALCON-C19	Facilitating Accelerated CLinical evaluation Of Novel diagnostic tests for COVID-19. Study limited to working with human tissue samples and other biological samples and data.	Secondary care	Open at WSH	WSH: 96 Nationally: 4,298

⁵Local update

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