

Update on COVID-19 research in Suffolk – 07/01/2021

Key Updates:

Newly NIHR UPH badged studies!

- **Xarelto: Rivaroxaban for high risk people with mild COVID-19** is part of a platform study which aims to assess safety and efficacy of different interventions in reducing mild COVID-19 recovery time and reducing disease progression in patients at high risk of developing serious complications from COVID-19. The intervention in this study is rivaroxaban (a blood-thinning medicine). Medical reports have shown that some persons with COVID-19 will have blood clots that form in the organs of the body – and blood clots in the lungs are potentially the most serious. It is hoped that by intervening early with a drug which thins the blood, it may prevent progression of mild symptoms to serious complications and severe disease. The Xarelto study has been Urgent Public Health badged and is looking to recruit 200 participants in the UK between mid-January and mid-March with the support from GP practices who are not already taking part in PRINCIPLE trial.
- **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 (Medicago; CoVLP)**
This Vaccine Task Force supported study is a phase 2/3, randomised, observer-blind, placebo-controlled, multi-country trial, which will be conducted in adults 18 years of age and older. Its aim is to evaluate the safety, efficacy and immunogenicity of a recombinant coronavirus-like particle vaccine (two doses of vaccine, at day 0 and day 21). It is anticipated that set-up activities will be progressed directly between the Commercial Sponsor and all sites which have previously been identified via the regional site identification process.
- **[The COVID-19 Clinical Neurosciences Study \(COVID-CNS\)](#)** This study aims to describe acute neurological and neuropsychiatric COVID-19 complications, and consequent medium-term neurological, mental health and cognitive outcomes.

Research results and other more general news:

- **3 peer reviewed publications from the Oxford and Astra Zeneca team published in December 2021 can be accessed via the Oxford Vaccine Group website:**
 - **[First peer-reviewed results of phase 3 human trials of Oxford coronavirus vaccine demonstrate efficacy](#)**
 - **[Oxford vaccine stimulates broad antibody and T cell functions](#)**
- **[RECOVERY trial finds no benefit from azithromycin in patients hospitalised with COVID-19](#)**

Azithromycin, a widely used antibiotic that also reduces inflammation (a key feature of severe COVID-19), was trialled in hospitalised 2582 patients

randomised to receive azithromycin and compared with 5182 patients randomised to usual care alone in this largest COVID-19 Urgent Public Health UK-wide trial.

A preliminary analysis available on [medRxiv](#) shows no significant difference in the primary endpoint of 28-day mortality (19% azithromycin vs. 19% usual care) and no evidence of beneficial effects on the risk of progression to mechanical ventilation or length of hospital stay. The results were consistent in different subgroups of patients. Full results will be made available as a peer-reviewed publication once follow-up has been completed for all participants. RECOVERY team did not study patients in the community and are not able to make conclusions about the effectiveness of azithromycin outside the hospital setting.

However, Azithromycin arm has just been discontinued on the PRINCIPLE trial (a nationwide clinical study, looking to find COVID-19 treatments for older people in the community).

- [Remdesivir likely to be highly effective antiviral against SARS-CoV-2 for some patients](#), according to a new study by a team of UK scientists who have shown how the drug benefitted a patient with COVID-19 and with a rare immune deficiency. The results from this case study were published in [Nature Communications](#).
- The Health Research Authority (HRA) are hosting a **Public Involvement in a Pandemic event on the 13th January 11-12:30pm via zoom**. Join to discuss lessons learnt from the UK COVID-19 public matching service. Register to join at public.involvement@hra.nhs.uk
- Please check out these [short films](#) from NIHR Research which address some of the concerns about taking part in vaccine trials for COVID-19.
- [How COVID-19-related healthcare changes affected patients with systematic autoimmune rheumatic diseases, including lupus](#). Read how decreased physician ability to help and increased patient reticence to seek help, created the 'perfect storm' for adverse outcomes, according to a study led by the University of Cambridge.
- [How should we re-design England's public health system beyond the Pandemic?](#) Professor Carol Brayne CBE and Professor John Clarkson from Cambridge Public Health argue that a radical rethink is long overdue.
- [Virtual ward: caring for COVID-19 patients at home could save lives](#). Read about this new model of care 'virtual ward': a system for supporting patients using home oximeters through phone or video calls.

The tables below give an overview of all COVID-19 research activity across Suffolk and NEE. 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	<p>Principle: Platform randomised trial of Interventions against Covid-19 with older people https://www.phctrials.ox.ac.uk/principle-trial</p>	<p>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.</p>	Primary Care	<p>Sites activated: Suffolk: The Peninsula Practice; The Two Rivers; Victoria Surgery The Christmas Maltings & Clements Practice Chesterfield Drive Haven Health Derby Road</p>	<p>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</p>	<p>35 across Suffolk & NEE practices Nationally: 3,139</p>
2	<p>FLU-CATS: Evaluation and refinement of pandemic</p>	<p>An observational study of</p>	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	pandemic influenza community 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 Local recruitment – 26 Nationally: 3,760
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	East Suffolk and North Essex NHS Foundation Trust selected to	MHRA approved study to restart Nationally recruited: 88

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

			across all health and social care sectors would be able to take part as participants	participate; WSH in set-up	
2	<p>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></p>	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	<p>Virus Watch</p>	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: 39 Howard House Surgery: 11 Oakfield Surgery:12 Stowhealth: 58 The Chesterfield Drive Practice: 56 Nationally recruited: 46,188
4	<p>Multi-centre European study of MAJOR Infectious Disease Syndromes (MERMAIDS): Acute</p>	An observational study aims to identify host and pathogen related determinants of severity of community acquired acute	This study will enrol participants in both primary	Trusts invited for expression of interest	Not yet set up

	Respiratory Infections in Adults	respiratory infections in adults.	care and secondary care.		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 complete	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, corticosteroids^[4], and Remdesivir, Hydroxychloroquine (arm closed; read more here), Tocilizumab, Dexamethasone, convalescent plasma . Other treatments may soon emerge that require	Secondary care; (Paediatric and neonatal arm to be added soon)	Open sites: ESNEFT (Ipswich and Colchester) WSH	WSH: 86 Ipswich Hospital: 186 Nationally : 24,045

^[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

		evaluation. The supply arrangements for each medicine for RECOVERY trial are described here .			
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:7 Nationally : 920
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	ESNFT (Colchester Hospital) :17 Nationally : 2,894

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;	ESNFT: 1352 WSH: 448 Nationally : 134,750
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: 26 WSH:1 Nationally : 7,345
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	Secondary care	Not open to new sites currently	Recruitment now complete Nationally recruited: 1,633

		other viral respiratory illnesses during the COVID-19 epidemic.			
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: 26 West Suffolk: 2 Nationally : 5,019
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	Secondary care	Open sites: WSH	There will be no consenting (no recruits) for this study as linked to another study

		is already in progress.			
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: 1 Nationally recruited: 189
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	Secondary care	Currently is being set up in secondary care –	WSH: 484 ESNEFT: 350

		<p>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.</p>		<p>all trusts expected to take part as part of Trust wide antibody screening processes</p> <p>Open sites: WSH ESNEFT</p>	<p>Nationally recruited: 30,606</p>
1 2	<p>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</p>	<p>Aims to establish a cohort of NHS-affiliated staff to investigate the short,</p>	<p>Secondary care</p>	<p>Open sites: ESNEFT</p>	<p>ESNEFT: 425</p> <p>Nationally recruited: 25,694</p>

		<p>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</p>			
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⁵Local update

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

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