

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

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.

COVID-19 Research findings and updates:

The [PRINCIPLE Trial reports](#) that **inhaled budesonide**, a common, inexpensive drug used for treatment of asthma shortens recovery times in COVID-19 patients aged over 50 who are treated at home and in other community settings. The results of the interim analysis of data from 1,779 participants showed the estimated median time to self-reported recovery for inhaled budesonide was 3.011 days shorter compared to usual care. 32% of those taking inhaled budesonide, compared to 22% in the usual care group, recovered within the first 14 days since being randomised into the trial and subsequently have remained well until 28 days. Participants in the budesonide group also reported greater wellbeing after two weeks. A pre-print of the research paper is available [here](#). The drug is the first COVID-19 treatment for use in the UK within a community setting and is now available on a case-by-case basis.

PRINCIPLE trial results on Inhaled Budesonide with COVID-19 Webinar on 20th April at 17:00. To hear directly from the PRINCIPAL trial leads about the treatment and the clinical trial results you can sign up [here](#).

[Favipiravir will be investigated within the PRINCIPLE trial](#) as another possible treatment for COVID-19 in people recovering at home and in other non-hospital settings. Favipiravir is an antiviral drug that has been licenced in Japan since 2014 to treat influenza. It works by inhibiting a viral enzyme called RNA polymerase, preventing viral replication within human cells. This viral enzyme is common to several viruses, including SARS-CoV-2, which causes COVID-19. The drug has shown positive results against SARS-CoV-2 in laboratory and animal studies, with small pilot studies in humans demonstrating some benefit in reducing symptoms and the duration of illness. Read more [here](#).

[BASIL+ Behavioural Activation \(BA\) for Social IsoLation](#) study is testing a practical treatment that explores how physical inactivity and low mood are linked, and result in a reduction of valued activity. The study team has adapted and manualised BA for older people with long term conditions who were required to socially isolate (including shielding) in response to Covid-19. The study is open at one community Trust and supported by the two GP participant identification centres in Norfolk and Waveney.

New COVID-19 studies:

[The COVID-19 Clinical Neuroscience Study \(COVID-CNS\)](#) will look at 800 UK patients who were admitted to hospital with COVID-19 and had neurological or neuropsychiatric complications, in order to understand how these problems occur and develop strategies to prevent and treat them. The study is open to recruitment at Cambridge University Hospitals in the Eastern region along other centres across the UK.

Other news of interest:

The [Living With Covid Recovery programme](#) An innovative digital treatment programme for people with Long Covid that is being rolled out to hospitals across the south of England. The programme is carried out through a tablet or phone app by patients after they have left hospital. The programme is being developed by the University College London (UCL) researchers with Barts Health NHS Trust and UCL Partners. [Read more.](#)

[Primary care practitioners feel unprepared to manage bereaved patients experiencing complicated grief: findings from a realist review](#) Dr Caroline Pearce from the Palliative & End of Life Care Group, Primary Care Unit, University of Cambridge discusses her recent research on complicated grief in primary care. See also [Briefing on bereavement care during the pandemic](#) featuring this research and the paper in [BMJ Open](#).

[Are the statistics of COVID trials understood by the public?](#) An interesting article from the Imperial College London on the public perception and understanding of the reported statistics from the vaccine trials.

[Evaluating COVID-19 vaccines outside of clinical trials](#) A discussion article published in *JAMA* about the ethics of trial design and conduct of COVID vaccines in the presence of vaccines that work and are being rolled out.

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

Please note that it is understood that all medications unless indicated below are sources and provided centrally for use in these trials.

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>74 across Suffolk & NEE practices Nationally: 4,775</p> |

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

| | | | | | |
|----|---|--|-------------------|--|---|
| 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 |
| 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 | The aim of the study is to determine the effectiveness of chloroquine/hydroxychloroquine prophylaxis in preventing symptomatic COVID-19 in | Secondary Care but with the expectation that frontline workers across all health and social care | ESNFT expected to take part | Not yet set up |

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

| | | | | | |
|----|---|---|---|--|---|
| | <i>Study being amended to look at other prophylactic treatments instead of chloroquine / hydroxychloroquine</i> | healthcare workers at risk of SARS-CoV-2 exposure. | sectors would be able to take part as participants | | |
| 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: 80 Oakfield Surgery: 22 Stowhealth: 84 The Chesterfield Drive Practice: 82 Nationally recruited: 56,732 |
| 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: 170 Ipswich Hospital: 397 Nationally: 39,503 |
| 2 | RECOVERY-RS (Respiratory support) | This study is aiming to determine if CPAP (continuous positive airway pressure) or | Secondary care | Open sites: Ipswich Hospital | ESNEFT:9 |

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/ | HFNO (high flow nasal oxygen) is clinically effective compared to standard care (excluding CPAP or HFNO). | | Colchester WSH | Nationally: 1,272 |
| 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: 4,401 |
| 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: 202,146 |
| 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: 72 WSH:1 Nationally: 12,198 |
| 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 | 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 |

| | | | | | |
|-----|--|--|----------------|---|---|
| | https://pan-covid.org/ | understanding natural history to guide treatment and prevention | | | Nationally: 7,392 |
| 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: 422 |
| 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: 598 ESNEFT: 352 Nationally recruited: 44,715 |

| | | | | | |
|-----|--|--|----------------|-------------------------------------|--|
| 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: 82 Nationally: 2,649 |
| 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. | 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: 4,338 |

⁵Local update

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