

The Primary Care Clinical Trials Unit is an integral part of the Nuffield Department of Primary Care Health Sciences at the University of Oxford. Our research themes are aligned with the departmental priorities on infectious diseases, cardiovascular and metabolic disease, behavioural medicine and other topics of major national and international importance.

Our goal is to become the world's leading Primary Care Trials Unit developing, delivering, interpreting and disseminating patient-facing primary care research to the highest international standards.

## Selection of studies on cardiovascular & renal research open for recruitment

### BARACK-D

Benefits of Aldosterone Receptor Antagonism in Chronic Kidney Disease

**Disease area:** chronic kidney disease

**Study details:** Few chronic kidney disease (CKD) therapies have proved effective in modifying the increased cardiovascular disease risk or the rate of renal decline in CKD. Accumulating data suggests that aldosterone receptor blockers may offer cardio-protection and delay renal impairment in patients with the CV phenotype in CKD. BARACK-D aims to determine the effect of aldosterone receptor antagonism on mortality and cardiovascular outcomes in patients with Stage 3b CKD. Patients will be randomised between the ARA (spironolactone 25mg o.d.) with routine care versus routine care alone; follow-up duration 36 months.

**Chief Investigator:** Professor Richard Hobbs

**GP practice recruitment:** Ongoing national recruitment via six NIHR Primary Care Research departments.

**Regions:** recruiting nationally.

**Patient recruitment:** Adults over 18 years with blood test results indicating CKD stage 3b.

**Contact:** [barack@phc.ox.ac.uk](mailto:barack@phc.ox.ac.uk)  
01865 617884

### OxRen

Oxford Renal longitudinal cohort study

**Disease area:** chronic kidney disease

**Study details:** A prospective population based study of CKD to examine the optimal methods for screening, cardiovascular risk prediction and interventions to prevent declining kidney function. The study will estimate the prevalence, incidence and progression of CKD from a demographically representative sample of the UK general population over a ten-year period. OxRen aims to improve screening and treatment options through better understanding of the disease, its prevalence and progression.

**Chief Investigator:** Professor Richard Hobbs

**GP practice recruitment:** Currently recruiting practices with a target of 11.

**Regions:** Thames Valley

**Patient recruitment:** Recruitment started in November 2013. Target of up to 550 patients per practice.

**Contact:** [oxren@phc.ox.ac.uk](mailto:oxren@phc.ox.ac.uk)  
01865 289290

### TASMINH4

Telemonitoring and/or self-monitoring of blood pressure in hypertension

**Disease area:** hypertension

**Study details:** Raised blood pressure is common. It causes very few symptoms but treatment can prevent the risk of stroke or heart disease. Decisions about how much blood pressure medication to take and when to change it are made by GPs and nurses taking blood pressure in the surgery. Our research aims to find out whether high blood pressure is better controlled using blood pressure readings taken by patients at home compared to clinic readings. Study participants will be asked to send their home readings to the surgery by post (self-monitoring) or by free text message (tele-monitoring) and the GP will adjust the medication if necessary to achieve the best health care for patients.

**Chief Investigator:** Professor Richard McManus

**GP practice recruitment:**

**Regions:** Thames Valley; Birmingham; South West Midlands; Eastern; West of England; Kent, Surrey, Sussex; Liverpool.

**Patient recruitment:** currently recruiting

**Contact:** [tasminh4@phc.ox.ac.uk](mailto:tasminh4@phc.ox.ac.uk) Tel: 01865 617 845



# Selection of studies on infectious diseases open for recruitment

## ARCHIE

early Antibiotic use in at Risk CHildren with Influenza

**Disease area:** Influenza

**Study details:** Double-blind randomised placebo-controlled trial to determine whether early treatment with co-amoxiclav reduces the likelihood of re-consultation due to clinical deterioration in 'at risk' children with influenza/influenza-like illness (ILI). ARCHIE will also include a nested cohort study to determine the potential impact of co-amoxiclav on long term antibiotic resistance. 'At risk' children aged six months to 12 years who present with ILI within the first five days of symptom onset will be recruited. The recruitment target is 650 children from across England. Recruitment will be seasonal, taking place October to March inclusive from primary care and ambulatory settings in secondary care. Baseline nasal and throat swabs will be taken; the nasal swab analysed for influenza, and throat swab for bacterial culture and sensitivity.

**Chief Investigator:** Dr Kay Wang

**Site recruitment:** Over 100 participating sites in England.

**Patient recruitment:** Target of eight patients per recruiting site during a flu season. Planned for flu seasons 2014/15, 2015/16 and 2016/17 if necessary.

**Contact:** [archie@phc.ox.ac.uk](mailto:archie@phc.ox.ac.uk)

**Tel:** 01865 617842



## HEAT

Helicobacter Eradication Aspirin Trial

**Disease area:** Aspirin users, specifically those with *Helicobacter pylori* (*H.pylori*)

**Study details:** A randomised controlled trial to investigate whether a one week course of *H.pylori* eradication will reduce the incidence of gastric ulcer bleed in patients using aspirin.

For patient recruitment a MiQuest search of GP computer databases is done to identify patients. Patients are then seen at their local GP surgery where a trained research nurse performs the consent visit. All breath test results and eradication treatment delivered by post. There are no face-to-face follow-up visits for patients; all follow-ups are done electronically. Patients are contacted annually for information regarding any hospitalisations in the previous year and GP records reviewed annually.

**Oxford Investigator:** Professor Richard Hobbs

**GP practice recruitment:** Currently recruiting. Target 48 practices per PCT.

**Regions:** Nottingham, Durham, Birmingham/Oxford, Southampton and Wales.

**Patient recruitment:** Currently recruiting with a target of 6,600 randomised patients across all regions

**Contact:** [HEAT@phc.ox.ac.uk](mailto:HEAT@phc.ox.ac.uk)

**Tel:** 01865 289336



## ATAFUTI

Alternative Treatments for Female Urinary Tract Infection

**Disease area:** female urinary infection

**Study details:** ATAFUTI is a double blind, placebo controlled, factorial randomised trial of a herbal remedy (*Uva ursi*) currently available over the counter with a traditional use licence although never subjected to a rigorous efficacy study. There is preliminary evidence suggesting it may provide symptom relief when used in acute UTI. This study will evaluate whether *Uva ursi* compared to placebo or the advice to take ibuprofen compared to no advice provide relief from urinary symptoms in adult women with suspected UTI. It will also evaluate if this resulted in reduced antibiotic use. Qualitative interviews will be conducted with GPs and patients to determine barriers to implementation of a delayed antibiotic prescription approach and use of a herbal medication.

**Sponsor:** Southampton University

**Chief Investigator:** Professor Michael Moore

**GP practice recruitment:** Target of 60 practices in total.

**Regions:** Thames Valley, Eastern, Kent, Surrey & Sussex, West Midlands and Wessex.

**Recruitment:** starting summer 2015



Thames Valley Primary Care Research Partnership

CTU Newsletter Spring 2015



# Selection of studies on infectious diseases currently on set-up

## ALIC<sup>4</sup>E

Antivirals for influenza Like-Illness? an rCt of Clinical and Cost effectiveness in primary CarE

**Disease area:** influenza

**Study details:** Open adaptive randomised design trial of usual best primary care versus usual best primary care plus oseltamivir. We are investigating the clinical and cost effectiveness of the addition of antivirals to usual care, starting initially with oseltamivir, but due to the adaptive design can add in new antivirals through out the three years of the trial. We are also looking at sub-groups and how they respond differently to the treatments, the adaptive design allowing us to analyse this throughout the trial. In addition we are testing a new point-of-care test for influenza. This will initially be done through collecting samples and sending them to a central laboratory, with the potential later of testing the suitability of use in GP surgeries themselves. Finally there is a qualitative aspect reviewing barriers to recruitment within infectious disease research.

**Chief Investigator:** Professor Chris Butler

**Site recruitment:** across Europe and Oxford, Southampton and Cardiff in the UK.

**Patient recruitment:** target of eight patients per recruiting site during a flu season. Planned for flu seasons 2014/15, 2015/16 and 2016/17 if necessary .

**Contact:** [alice@phc.ox.ac.uk](mailto:alice@phc.ox.ac.uk)

**Tel:** 01865 617866

## PRINCESS

Probiotics to Reduce Infections in CarE home reSidentS

**Disease area:** common infections

**Study details:** A double blind, placebo-controlled trial of probiotics to reduce common infections in care home residents. We are investigating the use of a daily probiotic supplement given to care home residents either in a drink or with food for a year to reduce the number of infections. Recruitment will be nurse-led through the care homes directly but we will be working with the associated GP practices to collect outcome data. Eligible participants will be invited to attend a baseline appointment at which informed consent or a consultee declaration will be obtained, baseline samples taken and baseline data recorded. Participants will be invited to attend a maximum of three additional appointments over a 12-month period. All participants will have two follow ups, one at three months and one at 12 months.

**Chief Investigator:** Professor Chris Butler

**Recruitment target:** 330

**GP practice recruitment:** care home based, target of 10 per region.

**Regions:** Thames Valley and Cardiff

**Patient recruitment:** aim of 15 recruits per care home.

**Contact:** [princess@phc.ox.ac.uk](mailto:princess@phc.ox.ac.uk)

**Tel:** 01865 289336

## PACE

Primary Care use of a C-Reactive Protein (CRP) Point of Care Test (POCT) to help target antibiotic prescribing to patients with Acute Exacerbations of Chronic Obstructive Pulmonary Disease (AECOPD) who are most likely to benefit

**Disease area:** chronic obstructive pulmonary disease (COPD)

**Study details:** Two arm individually randomised controlled trial. The aim of this trial is to determine whether the addition of a C-Reactive Protein Point-of-Care Test to current best practice leads to a reduction in antibiotic consumption for COPD exacerbations within four weeks post consultation without negatively impacting on COPD health status, compared with current best practice. We will also study the prevalence of resistant bacteria (throat swab), health utility, antibiotic prescribing and adverse effects during first four weeks, use of other treatments and cost-effectiveness.

**Chief Investigator:** Professor Chris Butler/Dr Nick Francis

**Regions:** Cardiff, Thames Valley and South Midlands, West of England and South London.

**Recruitment:** Starts in Autumn 2015.



# Selection of studies on behavioural medicine in follow-up

## BWeL

Brief intervention for Weight Loss

**Disease area:** obesity

**Study details:** Randomised control trial with two arms: practical support (offer of referral to a commercial weight management programme and one month review) and medical advice (control). Twenty-five percent of the UK's adult population is obese. However, GPs rarely discuss weight management with patients or support behaviour change. No trial has examined whether screening to identify overweight or obesity in adults and brief intervention are effective. Opportunistic recruitment is taking place.

**Chief Investigator:** Professor Paul Aveyard

**GP practice recruitment:** Recruited 64 practices took part.

**Regions:** Buckinghamshire, Oxfordshire, Bedfordshire, Hertfordshire, Northamptonshire, Norfolk, Gloucestershire, Swindon, Luton, Bristol and Warwickshire.

**Patient recruitment:** The trial recruited 1,879 participants and recruitment has now finished. We are currently in the follow up phase.



## WRAP

Weight loss Referrals for Adults in Primary Care

**Disease area:** obesity

**Study details:** A multicentre, randomised, controlled trial with parallel design to assess the clinical and cost-effectiveness of primary care referral to a commercial weight loss provider. The trial will evaluate three weight loss interventions that can be delivered in primary care; referral to a commercial provider for 12 weeks, referral for 52 weeks, and a brief intervention. The research will evaluate whether commercial provider interventions achieve significantly greater weight loss from baseline to 12 months compared to brief intervention by primary care providers. The trial is looking to recruit 1,200 overweight and obese adults in England, recruited by their local primary care provider.

**Chief Investigator:** Dr Amy Ahern

**GP practice recruitment:** Closed

**Regions:** Thames Valley, Western and Surrey & Sussex.

**Study stage:** Follow up phase.



## Coming soon...

## DROPLET

Doctor referral of overweight people to low energy treatment

**Disease area:** obesity

**Study details:** A randomised controlled trial to test the effectiveness of a GP referral for obese patients to a low energy liquid diet. We aim to recruit 270 participants and randomise them into one of two arms – to receive the Cambridge Weight Plan diet or usual care for weight management. Follow up takes place at six months and 12 months. The study is still in the set up phase.

**Chief Investigator:** Professor Susan Jebb

**GP practice recruitment:** In set-up.

**Regions:** Thames Valley.

**Patient recruitment:** Target 270 in total.



## Observational Studies open for recruitment

### **CANDID**

CANcer Diagnosis Decision rules

**Disease area:** lung and colorectal cancer

**Study details:** Observational study aimed to identify the most effective symptoms and examination findings for prediction and subsequent diagnosis of lung or colorectal cancer, in order to develop a clinical decision rule. There are few valid studies to assist decision-making in primary care, either to get patients referred quickly or making sure an anxious patient is effectively reassured.

The study is seeking to recruit two cohorts with symptoms that might suggest lung or colorectal cancer. Baseline information will be recorded and participants will be followed up after two years (notes review and search of relevant cancer registry). Participants are also invited to provide either blood or saliva samples and to answer a lifestyle questionnaire.

**Chief Investigator:** Professor Paul Little

**Regions:** Oxford, Southampton, Bristol, Manchester, Birmingham, Keele, London and Nottingham.

**Patient recruitment:** Currently recruiting. Target of 20,000 patients nationally and 2,500 per region.



### **Would your practice and patients like to be involved in our research?**

**Contact:** Ly-Mee Yu, PC-CTU Deputy Director Academic, or your local Primary Care Research Network

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**Phone:** +44 (0)1865 617199

**Thames Valley Primary Care Research Partnership**

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# With your help we successfully completed recruitment in the following studies Thank you for your cooperation

## **TOAST – Treatment Options without antibiotics for Sore Throat**

**Disease area:** sore throat

**Study details:** Multicentre double blind randomised, placebo controlled trial looking at whether a single dose of dexamethasone is a clinical and cost effective treatment for sore throat in primary care. 566 participants were recruited to the trial over a two year period. Recruitment was co-ordinated across the Thames Valley, Gloucestershire, Bristol, Northampton, Devon, Cornwall, Wiltshire and Hampshire. All follow up procedures have now been completed and final results are due later this year.



## **EDGE-COPD - sElf management anD support proGrammE for COPD**

**Disease area:** chronic obstructive pulmonary disease (COPD).

**Study details:** The EDGE programme comprised a pilot study and open randomised trial of a multi-component mobile-health based intervention compared with usual care to improve outcomes in COPD. With greater demands on health care resources in an ageing population, new solutions are being sought to provide integrated care pathways for the support and management of patients with long term conditions. The EDGE team developed a mobile-health (mHealth) telemedicine app, for use on tablet computers by patients self-managing their COPD.

**Regions:** Oxfordshire & Berkshire

**Trial update:** 166 patients were recruited through the community nursing service, pulmonary rehabilitation or via their GP, with moderate to severe COPD (FEV1 < 70%, GOLD classification). Follow up will be completed in July 2015.

**Chief Investigator:** Professor Andrew Farmer



## **EXPERT- EXPerience of a health website Evaluated in a Research sTudy**

**Disease area:** asthma, smoking and multiple sclerosis (carers)

**Study details:** The provision of reliable, relevant and timely health information for the public and patients is fundamental to the delivery of the NHS. People routinely get information on a new diagnosis or make health-related decisions from information found on the internet. We know relatively little about how people use and evaluate health information websites and therefore remain unsure whether, when and how the NHS should provide health information online. A randomised controlled study was conducted to inform these questions focusing on three exemplar conditions – asthma, smoking cessation and carers of individuals with multiple sclerosis.

**Regions:** Thames Valley, Western (Gloucester and Swindon).

**Trial update:** Recruitment was completed and the results are being analysed.

**Chief Investigator:** Professor John Powell

**EXPERT**

## Successfully completed studies

### **RCT<sup>2</sup> – Randomised Controlled pilot Trial of corticosteroid injection for shoulder pain**

**Disease area:** Shoulder pain

**Study details:** Single-blind, randomised controlled pilot trial of corticosteroid injection for shoulder pain. Eligible participants aged between 35–74 presenting to general practice with rotator cuff tendinopathy or adhesive capsulitis were randomised to receive an injection of either corticosteroid with local anaesthetic or local aesthetic alone. The primary outcome measures were designed to assess feasibility prior to conducting a larger clinical trial. The Oxford Shoulder Score questionnaire was used as a secondary outcome measure with participants completing this at baseline prior to the shoulder injection and then at four weeks and twelve weeks post injection.

**Trial update:** 40 participants were recruited and followed up from five GP surgeries over a period of six months.

**Chief Investigator:** Dr Tim Holt



### **MAC – Montelukast And persistent Cough**

**Disease area:** Persistent cough

**Study details:** A double-blind randomised placebo controlled trial of the use of montelukast for the treatment of persistent cough in young people and adults. Participants aged 16–49 with a persistent cough of two to eight weeks in duration were randomly allocated to receive a 28-day course of montelukast or placebo tablets and asked to complete a daily cough diary for two weeks. Participants were assessed at two weeks and four weeks to monitor the status of their cough. An oral fluid sample was taken from each participant and tested for whooping cough.

**Trial update:** Recruitment closed in September 2012 with 276 participants entering the trial from 25 general practices. 25% of participants tested positive for pertussis. The results are being analysed and will be circulated in the near future.

**Chief Investigator:** Dr Anthony Harnden



### **CAPS – Children And Persistent cough Study**

**Disease area:** persistent cough

**Study details:** The prevalence of whooping cough and *Mycoplasma pneumoniae* in school aged children with persistent cough was investigated in this observational study. Children between five and 15 years old who presented in primary care with a persistent cough of two to eight weeks' duration were recruited to the CAPS study. An oral fluid swab and throat swab were taken from each child. Swabs were sent to the London Health Protection Agency to be tested for whooping cough and *Mycoplasma pneumoniae*.

**Trial update:** 305 children were recruited from 22 GP practices in Thames Valley. The study concluded that pertussis can still be found in a fifth of school aged children with persistent cough and can cause cough in fully vaccinated children. The results were published in the *BMJ* and can be found on: <http://www.bmj.com/content/348/bmj.g3668>

**Chief Investigator:** Dr Kay Wang



### **AIRS – AutoInflation Randomised Study**

**Disease area:** glue ear

**Study details:** AIRS is an open randomised study of autoinflation in 4–11 year old school children with otitis media with effusion (OME) in primary care. Participants were randomised to receive standard care or autoinflation – inflation of a nasal balloon via each nostril three times per day for up to three months plus standard care. A total of 320 patients were recruited from practices across the Thames Valley, Western, HIOW and Cheshire CLRN.

**Chief Investigator:** Dr Ian Williamson, Primary Medical Care, University of Southampton.

**Local Investigator:** Dr Anthony Harnden



