Newsletter

Clinical Trials and Evaluation Unit Bristol

Autumn/Winter 2016

Welcome to the Autumn/Winter edition of the Clinical Trials and Evaluation Unit (CTEU) Bristol newsletter.

We have had a busy few months, with a number of studies in set-up and the early stages of recruitment.

We have also had a number of studies reach their recruitment targets which is fantastic news!

Studies in Recruitment

Study	Recruitment to date	Study	Recruitment to date
CORTISOL 2	13/60	ETTAA	19/48
INVITE	3/30	EVALUATE	0/30
ARCADIA	62/128	Victory	21*
Oxford Artery	199/200	RVENCH	76/100
By-Band-Sleeve	557/1341	Stem Cell	20/60
Bluebelle	342/330	TARGET	11/78
Ivan Follow Up	197/610	Template	35/110
AIRWAYS-2 (patients)	5922/9070	VEST	11/15
AIRWAYS-2 (paramedics)	1506/1500	Violet	132/498

Recruitment figures as of October 2016. Yellow indicates the study has reached the recruitment target. *National target acheived.

Trials in set up

VICI TRIAL

Peacock Study

Spotlight on: SKArF

The SKArF Study: Identifying proteins in heart tissue relating to atrial fibrillation

Atrial fibrillation (AF) is the most common heart rhythm disorder in the UK, estimated to effect over 1 million people. AF is associated with reduced life expectancy, mainly due to the increased risk of stroke. Current AF treatments include antiarrhythmic drugs and surgical procedures. Unfortunately, many effective antiarrhythmics can have serious side effects due to their activity in heart chambers known as ventricles.

Professor Marrion's research group has found proteins called SK channels, which are thought to contribute to heart activity in other heart chambers known as the atria. It is suggested that these channels could be a potential target for the development of new antiarrhythmics without the side effects at the ventricles.

This study will collect surplus heart tissue from patients undergoing cardiac surgery, and test these atrial SK channels to see how they affect the electrical activity of the heart in patients both with and without AF.

SKArF is a single centre study looking to recruit 90 adult patients who attend the Bristol Royal Infirmary for elective cardiac surgery over 12 months. The study is funded by the British Heart Foundation. The Chief Investigator is Prof Raimondo Ascione, and the University researchers will be led by Prof Neil Marrion.

News

In September we learned that the joint bid from UH Bristol and the University of Bristol to be an NIHR Biomedical Research Centre had been successful. The five year award, worth £21.8M, will begin in April 2017 and will be split between 5 themes; Cardiovascular Disease, Nutrition, Diet and Lifestyle, Surgical Innovation, Mental Health and Perinatal and Reproductive Medicine. There are also eight cross cutting themes.

The By-Band-Sleeve study reached an important milestone in September, recruiting the 500th participant, and has since randomised a further 57 participants! The study aims to compare the effectiveness and cost-effectiveness of the three main types of bariatric surgery; gastric Band, gastric Bypass and Sleeve gastrectomy. The primary outcomes are weight loss and health-related quality of life over 3 years. The study is approaching its 4th year and has 11 recruiting sites. Further information can be found on the study website **http://www.bybandsleeve.bristol.ac.uk.**

In September, the Bluebelle pilot RCT opened its 5th and final recruiting site in Worcester. In October, the study reached its target of 330 participants recruited and randomised to "no dressing", a simple dressing or "glue-as-a-dressing" on primary closed wounds following elective and unplanned abdominal surgery. Recruitment continues until the end of November.

The Thermic-3 study is currently being set up and will begin recruitment next year. The study will compare warm and cold cardioplegia temperatures in children, looking at the effects on recovery after cardiac surgery. The 'cardioplegia' is a solution used to protect the heart and keep it still during cardiac surgery. Both cardioplegia temperatures have been used in children, but as the two techniques have not yet been directly compared in children we do not know which is best.

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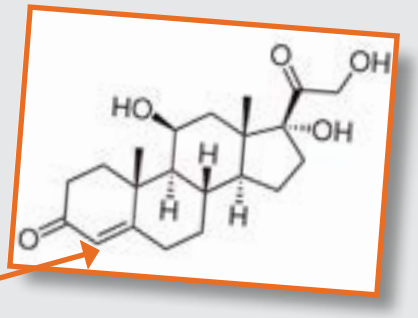
CORTISOL-2

The CORTISOL-2 trial is recruiting well and has nearly reached its 20 patient target.

The aim of this study is to measure the cortisol profile in patients who are critically ill for 2 or more days after their heart surgery so that we can see not only how much cortisol they are producing, but also how the rate of production varies over time. Knowing this information will help clinicians to give steroids (if needed) in a more tailored way.

The study involves taking blood samples for 24 hours at 10 minute intervals.

The running of CORTISOL-2 involves a team of research nurses, anaesthetists, clinicians, intensive care nurses and lab staff, assisted by trial coordinators.



Cortisol structure

We are looking for nurses to help with sample collection. This is paid as band 6 on bank. If you are interested, please contact the Cardiac Research Nurses on 0117 342 1143.

Day in the life of a Paediatric Research Nurse

Our Paediatric Research Nurses are responsible for the screening and recruitment of patients, and data collection for clinical trials involving children with cardiac problems. They act as clinical experts during development of a trial protocol, design information sheets and CRFs, as well as helping to interpret the data once analysed. Below are some of the tasks that the nurses are typically involved in:

SET-UP

- Feasibility of studies
- Costing of tests
- Develop trial documentation
- Work with co-ordinators to develop validation rules

RECRUITMENT

- Screen clinic patients for eligibility
- Lead and manage the consenting process with the child and family
- Consent patients and parents onto study
- Communicate patient's participation to the wider team

DELIVERY

- Check eligibility and consent
- Liaise with surgical team
- Ensure correct samples are obtained and transported to the lab as appropriate
- Data collection
- Follow up

ANALYSIS

- Work with co-ordinators and statisticians to resolve data queries
- Contribute to writing of study publications

This unit receives National Institute for Health Research CTU Support Funding. This funding has been awarded to support the unit in developing and supporting NIHR trials

University Hospitals Bristol NHS NHS Foundation Trust

UKCRC Registered Clinical Trials Units

Funded & supported by NIHR

IVAN follow up

The IVAN Follow Up study aims to collect long-term information (5-7 years) for participants in the Inhibition of VEGF in Age-related choroidal Neovascularisation (IVAN) trial. It aims to answer additional research questions of major importance to the NHS about the management of wet age-related macular degeneration (AMD) in the longer term.

We spoke to Bristol Study coordinator Dawn Phillips about this important study which has recently started recruiting.

What does the study involve for those taking part?

Participants have several options to choose from. They can choose to attend a single research appointment where they will complete a questionnaire, answer questions about their medical history, undergo visual acuity tests and have photographs and scans taken of their retina. Alternatively they can choose to complete a questionnaire by post and allow research staff to access their ophthalmology data and imaging history from when IVAN finished until the present day. Participants also have the option to withdraw and not participate which will not have any effect on the medical care they receive.

How many participants are you aiming to recruit?

The IVAN study recruited 610 participants so we will be collecting data on as many of these participants as possible. We are approaching all surviving participants. For those participants who have died, are too ill to participate in the active part of this study, or who are "lost to contact" we will be collecting data from their medical notes to assist in answering the study outcomes. Each of the IVAN trial participants consented to their data being used for long term follow up with the exception of participants who withdrew from the study so we are confident that the remainder will participate.

Which sites are involved?

The study is overseen by our Chief Investigator Professor Usha Chakravarthy in Belfast. Out of the 23 sites who participated in IVAN, 20 are participating in IVAN Follow Up. The study opened on 25th May 2016 and to date 16 sites are open and recruiting.

We are working with the remaining 4 sites to get them open as soon as possible. The response by participants to the invitation letters and questionnaires that have been sent out so far has been very good (41% have declined to allow us to collect data), and we are confident we can meet the aims of this very important and worthwhile study.

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