CTEU Bristol Newsletter

Clinical Trials and Evaluation Unit Bristol

Autumn/Winter 2017

Welcome to the Autumn/Winter edition of the Clinical Trials and Evaluation Unit (CTEU) Bristol newsletter, which includes news and updates on the studies undertaken by the unit.

UKCRC Registered Clinical Trials Units

UKCRC Registration approved until 2022

Studies in Recruitment

Study	Recruitment to date	Study	Recruitment to date
ARCADIA	66/128	PEACOCK	10/78
BY-BAND-SLEEVE	875/1341	ROMIO	63/406
ETTAA	35/35	STEM CELL	42/60
EVALUATE	10/30	SKaRF	10/30
INVITE	9/60	TARGET	28/78
OMACS*	959	VICI	77/104
OXFORD ARTERY	196/200	VIOLET	266/498
MARS2	92/328		

Recruitment figures as of October 2017. *No target in place for this study.

Recruitment Targets Reached

Bluebelle study

TEMPLATE STUDY

CORTISOL 1 & 2

IRWAYS 2

UKTMN Annual Meeting 10th October

In October five trial coordinators from the CTEU attended the 20th annual meeting of the UK Trial Managers Network (UKTMN) in London. The meeting gave the team the opportunity to hear about developments in trial management, including updates from the HRA and NHS Digital. The event was a great networking opportunity as trial managers from across the UK were in attendance, and interactive workshops enabled the team to share ideas and tips on topics such as engaging sites and optimising patient and public involvement. It was a valuable and highly informative meeting and the team would recommend it for anyone involved in setting up and running clinical trials. More information on the UKTMN can be found here: http://www.tmn.ac.uk/

CTEU Trial Managers at UKTMN Annual Meeting

What's New in the CTEU

MONARCH STUDY
MONITORING AMD AT HOME

We are setting up the Monitoring for neovascular Age-related macular degeneration (AMD) Reactivation at Home (MONARCH) study led by Co-Chief Investigators Dr Ruth Hogg (Queen's University Belfast) and Professor Barney Reeves (Bristol CTEU). MONARCH is a diagnostic test-accuracy study designed to find out whether home monitoring tests can detect when neovascular AMD needs to be treated can perform as well as the surveillance tests currently carried out at hospital check-ups.
Participants will be provided with an iPod touch and a mobile broadband device. They will be asked to complete 3 vision tests every week at home. Two of these use vision test software apps, the other involves reading a paper journal. Participants will be seen by hospital eye service clinics as per their usual care plan and care teams will be "blinded" to the results of the home monitoring tests. Data will be collected from the iPod touch devices remotely via the mobile broadband devices provided. The study will open at 5 UK sites.
MONARCH is funded by the NIHR Health Technology Assessment Programme (HTA) (15/97/02), and sponsored by The Queen's University Belfast.

CIPHER STUDY

During abdominal surgery, it is sometimes necessary to divert faeces from the bowel by forming a stoma. Unfortunately, the formation of the stoma can be associated with future complications, including the risk of developing a parastomal hernia (PSH). A PSH is an incisional hernia, that allows protrusion of abdominal contents through the abdominal wall defect causing a bulge in the skin. PSH are relatively common and affect approximately 40% of patients within 2 years of their bowel surgery, with both patient and surgical factors believed to influence the development of PSH. Complications of PSH can be severe and are known to negatively influence patients' quality of life. This study aims to establish the incidence of PSH during a minimum of 2 years follow up and evaluate the effects of key technical surgical steps during stoma formation on the risk of subsequent PSH development. The CIPHER study is in set up and due to start recruitment in December 2017.
This is an NIHR HTA funded study (14/166/01), sponsored by Royal Devon and Exeter NHS Foundation Trust and led by Dr Neil Smart.

GAP STUDY

Gabapentin is a medicine used to treat epilepsy and long-term pain. Recently, doctors have started to use gabapentin to control short-term pain after surgery, with the aim of reducing the amount of other drugs, such as opioids, needed to maintain good pain relief. Opioid drugs (for example morphine) are commonly used to control pain after surgery, but they can cause side effects such as nausea and confusion, changes in breathing and a reduction in coughing, which can lead to a slower recovery.
The GAP study will recruit 1500 patients having heart, lung or abdominal surgery. Patients will be randomised to receive either gabapentin or a placebo just before surgery and for two days following surgery. This study will determine whether giving patients gabapentin around the time of surgery results in improved pain control, faster recovery from surgery and fewer side effects from opioid drugs.
GAP is an NIHR HTA funded study (15/101/16), led by Dr Ben Gibbison and Professor Chris Rogers, and sponsored by University Hospitals Bristol.

GAP Study Team

Produced by the CTEU Newsletter Group: Abby Willcox, Hana Tabusa, Jade Salter-Hewitt & Maddie Clout

University of BRISTOL

Spotlight on PPI

Our Public and Patient Involvement (PPI) lead is Noreen Hopewell-Kelly. Noreen is responsible for engaging with members of the public and patients to help guide the research that the unit undertakes. Involvement can take the form of participation in a Public and Patient Advisory Group (PAG), or joining a study steering committee and having oversight of how a specific study is run. Noreen also undertakes public engagement work, such as running logo competitions with staff and local schools.

There are 3 main PAGs that people can join. Each group meets four times a year

- Young Persons Advisory Group (aged 8 – 16 years)
- Parent Advisory Group
- Public and Patient Advisory Group.

During these meetings, attendees may review patient-facing documents, pilot surveys, discuss trial design or help us decide what research to do next. There are also topic-specific PAGs, which have looked at heart failure, aortic valve replacement, intractable angina and anti-platelet drugs – these groups are often made up of patients with a particular interest in, or experience of, the topic discussed.

If you would like any of your work considered at an upcoming PAG, please email noreen.hopewell-kelly@uwe.ac.uk or see http://cteu.bristol.ac.uk/ppi/home/ for more information.

Members of the PPI Team, and logos from a comptetition with a local school.

Contact us!

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Thermic 2 Study Results

In children requiring cardiac surgery with cardiopulmonary bypass (CPB), normally the blood is cooled during the procedure, with most operations performed at 28 ºC (cold). The main rationale is to protect organs (including brain, kidneys, heart) from ischaemic injury by reducing the metabolic rate. This is reflected in decreased oxygen consumption. Previous research in adults suggested it could be better to keep the blood at normal body temperature (warm) during the operation. However, the conclusions drawn from such studies cannot be directly applied to children. In Thermic-2 we wanted to compare warm and cold CPB and look at their effects on children's recovery. 141 children and their parents gave consent to take part in the study.

The main study results show that the length of hospital stay, ventilation time and use of cardiac support drugs were all very similar for children receiving either warm or cold CPB.

We found some slight differences between the warm and cold CPB in some of the other things we looked at:

- Children who received warm CPB had on average slightly more blood loss than those who received cold CPB (approximately 30 ml more).
- Children who received warm CPB had slightly better kidney function in the hours immediately after surgery, but the groups were similar by two days after surgery (see graph below).
- For children aged under one year, some of the blood tests that measure brain function gave slightly better results for children who received cold CPB. This difference was only found in the 48 hour period after the operation. 3 and 12 months after surgery brain function tests did not differ between the groups. This difference was not observed in children aged over one year.

The Thermic-2 study results suggest that both warm and cold blood for CPB during cardiac surgery sre safe and effective. The results will be published soon and have been used to inform THERMIC-3 study which is now in set-up.

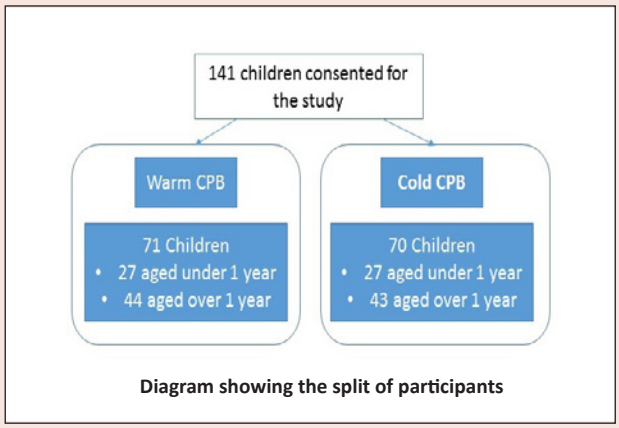
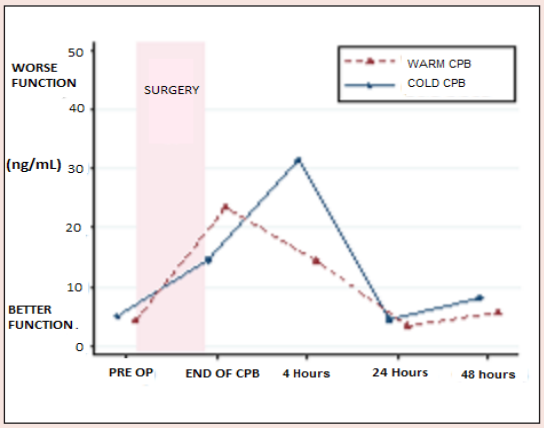


Diagram showing the split of participants



University Hospitals Bristol NHS Foundation Trust
UKCRC Registered Clinical Trials Units
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