Spring/Summer 2017

CTEU Bristol Newsletter

Clinical Trials and Evaluation Unit Bristol

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

Studies in Recruitment

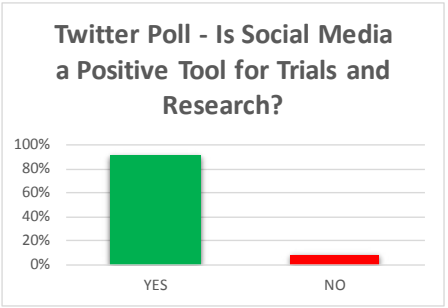
Study	Recruitment to date	Study	Recruitment to date
CORTISOL 2	23/20	ETTAA	30/48
INVITE	5/30	EVALUATE	6/30
ARCADIA	64/128	CORTISOL 1	62/60
OXFORD ARTERY	170/200	RVENCH	97/100
BY-BAND-SLEEVE	704/1341	STEM CELL	27/60
VICI	22/104	TARGET	19/78
IVAN FOLLOW UP	527/525	TEMPLATE	72/110
AIRWAYS-2 (patients)	7984/9070	ROMIO	15/406
AIRWAYS-2 (paramedics)	1522/1500	VIOLET	184/498

Recruitment figures as of March 2017. Yellow indicates the study has reached the recruitment target.

The BY-BAND-SLEEVE Study has passed the half way point in recruitment

BLUEBELLE has been 'data locked' and the data are now being analysed

A recent Twitter poll showed that a majority of people thought social media was a positive tool for research



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Trials in set up

CIPHER STUDY

GAP STUDY
GABAPENTIN IN POST SURGERY PAIN

Each year, **International Clinical Trials day** is celebrated in order to inform people about clinical research.
20th May is the day that the first clinical trial was started by James Lind in 1747. As a ship's doctor on HMS Salisbury, he carried out experiments to discover the best treatment for scurvy.

Spotlight on: CORTISOL 2

The CORTISOL-2 study has finished recruiting! In total the study recruited 20 patients. The aim of of this study this was to measure patterns of the steroid hormone cortisol in patients who are critically ill on intensive care after their heart surgery, and involved taking blood samples for 24 hours at 10 minute intervals.
We were looking at not only how much cortisol they produced, but also the pattern of production. Knowing this information will help clinicians decide whether to give steroids when patients are critically ill and, if yes, how to give them in a more tailored way.
This was the first study in the world to look at these profiles in critically patients. The results of this study will be available later this year.
We would like to thank the Cardiac Surgery Research Nurses and all the staff involved with collecting and processing the samples.

VICI Update

VICI TRIAL

Chronic Serous Chorio-Retinopathy (CSCR) occurs when fluid spontaneously gathers under the retina in the eye. It can lead to permanent vision loss in about a third of cases. The cause is unknown and there are no proven treatments. Recently a few patients have responded to treatment with a drug called eplerenone, which removes the subretinal fluid. However, information on the long term benefit and safety of eplerenone is lacking. The VICI trial aims to compare eplerenone plus usual care vs. placebo plus usual care for patients with CSCR in a double blind multi-centre RCT. The trial began recruiting in December 2016. So far 16 of 22 sites are open and 22 patients have been randomised (target 104). CTEU is coordinating this NIHR EME-funded study, which is sponsored by University Hospital Southampton and led by chief investigator Prof Andrew Lotery.

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IVAN Follow Up Response Rate

Patients who participated in the original IVAN study have responded enthusiastically to invitations to take part in a follow-up study, which aims to collect long term information (5-7 years) on participants with wet age-related macular degeneration (AMD). The IVAN study had a factorial design with patients randomised to receive either Lucentis® or Avastin®, and to a monthly or discontinuous treatment regime for 24 months.
38% of participants have attended a study appointment between May 2016 and March 2017. Retrospective data is being collected on 62% of participants, and a total of 275 Quality of Life Questionnaires will have been completed. All 20 open sites are busy entering data onto the electronic databases and uploading ophthalmic images to the grading centre in Belfast for analysis. We have received confirmation that our request to extend IVAN Follow Up has been approved by the HTA. The findings and final report will be available in February 2018.

STUDY RESULTS

COPTIC

Bleeding after cardiac surgery is common and is associated with decreased health and increased mortality. In the COPTIC study we compared how well a panel of 28 blood test results could predict bleeding, compared to prediction using only patient characteristics such as procedure, age and sex.

"Clinical concern about bleeding" occurred in 449 (25%) of 1833 UHBristol patients recruited between March 2010 and August 2012. Statistical models using only a panel of blood tests or only patient characteristics correctly predicted if there was, or was not, "clinical concern about bleeding" in a similar proportion of patients (1394 (76%) v. 1407 (77%)). Adding the results of the blood tests to the model based on patient characteristics improved the prediction to 78% but this was only an additional 18 patients.

We concluded that the panel of blood test results can predict bleeding in cardiac surgery patients, but they offer little improvement in prediction compared to patient characteristics alone.

HARVEST

During coronary artery bypass grafting surgery, vein grafts removed from other parts of the body are used to bypass diseased arteries in the heart and improve blood flow. However, as many as 40% of vein grafts become blocked within 12 years.

Currently, grafts are prepared by removing the surrounding fat when the vein graft is removed (conventional harvest). The vein is then tested for leaks by filling the graft with fluid at a high pressure. Alternative methods include removing the graft with the surrounding fat (pedicled harvest), and testing for leaks at a lower pressure.

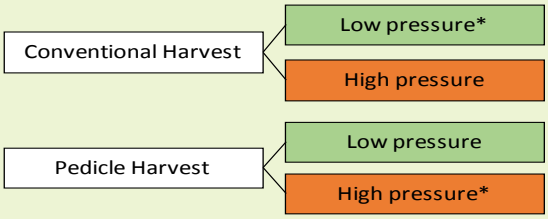

Fig. 1. Harvest groups
*Significantly reduced vein wall thickness at 12 months

The Harvest Trial was designed to test the vein graft removal/preparation strategies by randomly allocating patients to combinations of the above methods and assessing vein graft disease 12 months post-operatively (see figure 1). Results showed that for patients undergoing conventional harvest, vein wall thickness was reduced at 1 year follow up if the vein was tested for leaks using low pressure compared to high pressure.

PASPORT

During cardiac surgery, oxygen levels are monitored to make sure that a patient has enough oxygen. Current practise is to monitor the oxygen supply in the blood to show when the body is not getting enough oxygen and whether a blood transfusion is needed.

The PASPORT study looked at a new method of oxygen monitoring which monitors oxygen levels in specific organs, such as the brain, to see if this improves the cognitive function and health of patients after their operation.

The study recruited 204 patients in three centres and found that:
- Cognitive function after surgery was similar between the two groups.
- The number of patients who experienced any infection, stroke, heart attack, acute kidney injury or breathing complication was not significantly different between the groups. However, the proportion of patients who had any of these events was lower in the new method of oxygen monitoring group (34% v. 48% in the current practise group).
- Time in hospital was similar between the two groups, and the patients reported a similar quality of life after the operation.
- Blood and urine tests showed similar results between the two groups.

We concluded that using the new method to monitor oxygen levels in the brain, does not have any additional clinical benefits compared to current practise in adult cardiac surgery patients.

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

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