



Joint SBNS / BNTRC Academic Newsletter October 2020

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Welcome

Welcome to the fifth joint academic newsletter from the **Society of British Neurological Surgeons (SBNS)** Academic Committee and the **British Neurosurgical Trainee Research Collaborative (BNTRC)**.

This newsletter includes updates on;

- Recent research news
- Currently recruiting trials in neurosurgery
- Future trials under development
- BNTRC projects
- Dates for up-coming research events

Please get in touch if you have any questions about information in this newsletter, you would like your trial to be included or you would like to contribute to future news via Carole Turner, SBNS Research Manager clt29@medschl.cam.ac.uk or Dan Fountain, BNTRC Chair dan.fountain@gmail.com

News and events

UK neurosurgical research has inevitably been affected by the events this year and the majority of trials recruiting have been Covid-19 related, whilst the remainder were placed on hold. Although non-Covid trials were unable to recruit there are an impressive number of new NIHR multicentre neurosurgical trials which have been approved for funding this year and are now all in the set up phase.



Martin Wilby will be reporting the results of the NERVES Trial (Nerve root block versus surgery for the treatment of radicular pain secondary to a prolapsed intervertebral disc herniation) at the virtual SBNS meeting on 23rd October, not to be missed!!!

Recruitment is restarting at most sites after completion of local risk assessments and it is hoped that all trials will be resumed soon, subject to no new nationwide restrictions.

BNRG (Cardiff 2020)

Unfortunately the 2020 BNRG meeting has been cancelled. It was felt that the loss of face to face contact along with many impromptu discussions usually forthcoming at this event, would mean that the meeting would not be viable. We plan to resume the BNRG with a meeting in Cardiff, November 2021.

Covid related trials

At the outbreak of COVID, SCIL-SAH, like all other trials was stopped. At the same time it became clear to the SCIL team of the potential role of Anakinra, a cytokine antagonist, in controlling the “cytokine storm” that causes such harm and leads to the need for ICU management and increased mortality. Within the space of a weekend, we had

entirely repurposed the trial, including all the relevant regulatory paperwork, ready to apply for the UK stores of SCIL-SAH Anakinra and placebo to be run a randomised blinded study of drug v placebo in 400 patients (200 per arm) in a selected group of pre-ICU patients.

The study was not supported as the view at national level was that there should be only one centralised trial of Anakinra (as with many other treatment options) and that was, and is, REMAP-CAP. We did however achieve some success. The SCIL team worked closely with Prof Tony Gordon, UK CI of REMAP-CAP to advise and importantly modify the proposed dose regime for this trial. We published a comment article in *Lancet Rheumatology* advising on important considerations for Anakinra in clinical trials ([https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913\(20\)30160-0/fulltext](https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913(20)30160-0/fulltext)) and a further article in *BMJ Open* on improving clinic prediction models in COVID-19 (<http://bmjopen.bmj.com/cgi/content/full/bmjopen-2020-041983>). We achieved funding for a Manchester based trial randomising patients with COVID-19 to either subcutaneous or intravenous Anakinra. This trial has halted in July due to lack of patient numbers but hopes to resume.

Andrew King

Further Covid-related trials:

The AC and BNTRC are supporting two national COVID studies from the GlobalSurg programme in Birmingham:

- COVIDSurg – Mortality and pulmonary complications in patients undergoing surgery with perioperative SARS-CoV-2 infection: an international cohort study *Lancet* 2020 Jul 4;396(10243):27-38.
- COVIDSurg-Cancer-Neuro – BNTRC / SBNS Academic Committee will lead on writing manuscript for all data

The AC and BNTRC have developed three national COVID studies

- COVIDNeuroOnc – manuscript submitted to *Neuro-Oncology Advances*
- COVID CNSMDT – published in *BMJ Open* (<https://bmjopen.bmj.com/content/10/8/e040898.long>)
- COVID-SBNS-BNTRC – national audit of surgical activity in April 2020 and COVID mortality

Currently recruiting multi-centre trials

ROAM: *Radiation vs Observation following surgical resection of Atypical Meningioma: a randomized controlled trial*

There are now 58 sites open with a total of 124 patients currently recruited, 67 from the UK, 47 from European and 10 from Australia.

The trial restarted at the beginning of July and currently 20 sites are re-opened to recruit. Recruitment was due to end in Sept 2020 but the team propose to request an amendment to the funder: 12 month extension for recruitment, a reduction of follow up from 5 years to 4 years and a reduction in recruitment target to 155

Please visit the website for further updates www.roam-trial.org.uk



PRaM-GBM Study: *Predicting sites of treatment failure and tumour recurrence in the invasive margin of glioblastomas*

113 patients have been recruited of which 49 have disease progression. 65-70 are required to develop a prediction model for glioblastoma progression. There has however been approval granted for a 12 month no cost extension to continue until September 2021.

If you wish further information or to register interest please contact

Stephen Price sjp58@cam.ac.uk or trial coordinator Julia Cook julia.cook@addenbrookes.nhs.uk

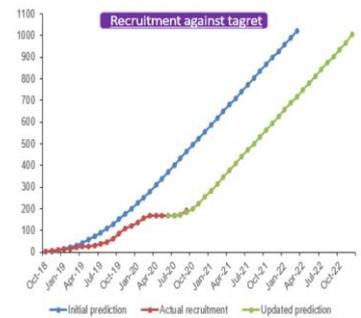


SCIL: *Interleukin-1 receptor antagonist in the treatment of aneurysmal subarachnoid haemorrhage*

A randomised double blind placebo controlled phase III trial with a target cohort of 1000 patients.

The study was restarted in September after the Covid-19 halt and has already recruited a further 19 patients, bringing the total to 193 patients.

A successful investigator meeting was held on 7th September. If anyone would like a copy of the PowerPoint presentations please contact a member of the study team. For further details or to express interest to join please contact either Andrew King Andrew.King@manchester.ac.uk or the trial manager Helen Bradley Helen.Bradley@christie.nhs.uk



GLOBAL NEUROTRAUMA:

The Global Neurotrauma Outcomes Study (GNOS) has been a global success thanks to an overwhelming interest from sites all over the world - 205 sites from 61 countries. It is a prospective, multi-centre, international cohort study of outcomes following emergency surgery for TBI with the aim to compare outcomes for emergency surgery for traumatic brain injury between high and low Human Development Index (HDI) countries. As the next step the group are planning to launch GNOS-X looking at outcomes after traumatic spine injury (TSI). GNOS has also paved the way for the implementation of the Global Epidemiology and Outcomes of TBI Registry which is now being piloted. The WFNS endorsed initiative will map the pre-hospital, acute in-hospital, and post-acute care of TBI patients and will be used for defining the contemporary case mix and outcomes of TBI patients. The establishment of a registry is a critical element of the long-term sustainability of Global Neurotrauma efforts, as it will be utilised by clinicians in local quality improvement projects and research.



Further ongoing trials:

HIFU

High intensity ultrasound for the treatment of sacral tumours

CI: Stana Bojanic, Oxford

CEREBRAL MUTISM STUDY

UK Contact: Conor Mallucci

Multi-centre trials funded and in set up

TRAUMA

MAST

Pharmacological management of post-traumatic seizures

CI: Peter Hutchinson

Trial Coordinator: Samantha Lawes Samantha.lawes@addenbrookes.nhs.uk

ONCOLOGY

STOP'EM

Surgeons Trial of Prophylaxis for Epilepsy in Meningiomas

CI: Michael Jenkinson

FUTURE-GB

Adult RCT of intraoperative DTI navigation + intraoperative ultrasound versus standard care for pts undergoing tumour resection

CIs: Dipandar Nandi/Sophie Camp/Puneet Plaha

SCARF-BT

Social cognition assessment and rehabilitation for families with brain tumours

CI: Stephen Price

VASCULAR

CARE*CIs Rustam Salman/Neil Kitchen**Active versus conservative management of cavernomas*Trial Coordinator: Elaine Kinsella CARE.Trial@ed.ac.uk

SPINE

RECEDE*CI: Mark Kotter, Cambridge**Regeneration in cervical degenerative myelopathy*Trial Coordinator: Daniel Alvarez-Berdugo daniel.alvarezberdugo@addenbrookes.nhs.uk**DENS***CI: Paul Brennan**Duration of External Neck Stabilisation following odontoid fracture in older or frail adults:
a randomised controlled trial of collar versus no collar*

Trials closed to recruitment

RESCUE-ASDH: Rescue for Acute Subdural Haematoma trial

Recruitment is now complete and data cleaning is now in progress. The plan is for hard lock and data analysis to start within the next few weeks.

Currently completed trials

DEX-CSDH: Dexamethasone in Chronic Subdural Haematoma trial

The manuscript is with the journal reviewers. The team are hopeful that the results will be announced in the very near future.

Future proposed trials

FUSION4DCM: Posterior decompressive surgery with fixation for degenerative cervical myelopathy**SWITCH:** surgery versus conservative management for spontaneous ICH**Cervical spine immobilization following blunt trauma:** Passed the first stage of funding process – is now in the second stage

BNTRC update and projects

This has been a challenging year for the BNTRC, but all of our projects have continued to progress with two new studies now open to recruitment. Our 2020 project call is open.

2020 Project Call

The 2020 BNTRC project call is currently open! This year we will be selecting two further projects to add to our portfolio of collaborative studies. For this call, we will be accepting proposals for randomised controlled trials (RCTs) to work up for competitive funding. All trainees / junior staff are welcome to submit proposals. If chosen, we will provide a trainee mentor from the BNTRC committee with experience in clinical trials and, if necessary, a consultant mentor from the SBNS Academic Committee to support your application to funding, design, and delivery.

Projects can be submitted using a submission form available on our website (www.bntrc.org.uk). The deadline for submission of projects is **Midnight Saturday 31st October 2020**. The BNTRC will then shortlist projects and announce these results in early November. Those with shortlisted projects will be invited to present their project proposal at a virtual workshop at the end of November. A panel from the SBNS Academic Committee and NIHR clinical trials units

will judge and score the proposals. The audience attending the workshop will also be able to vote, with scores incorporated into the final ranking.

As part of our project call and to increase awareness of neurosurgical RCTs, a webinar about UK trainee led neurosurgical studies will take place mid to late October via Zoom. Please watch this space for more information!

Ongoing projects (full details of ongoing projects are available on our website www.bntrc.org.uk)

- *UCES (Understanding Cauda Equina Syndrome Study)* – One year follow up is complete. Data checking and cleaning is in progress. Please could anyone with outstanding data requests return the requested information as soon as possible so that we can plan to lock the study database for analysis.
- *UK Cranioplasty Study* – This study is now complete and the manuscript is currently being revised for resubmission to *Neurosurgery*.
- *UK-C1S (The UK Chiari 1 Study)* – The study opened for recruitment in two units in October 2020, with 16 other units awaiting local R&D approval and another 10 awaiting REC approval. The study protocol has been submitted to BMJ Open.
- *IMPACT (Incidental Meningioma: Prognostic Analysis Using Patient Comorbidity and MRI-Tests)* – Data collection guides and video are being finalised for launch end of the month, with 36 Centres in 11 countries recruited. The study protocol is currently being prepared for submission to BMJ Open.

Pillars of Neurosurgery

In order to encourage academic discussion across disciplines and units around the country, we have recently started the 'Pillars of Neurosurgery' academic journal club, a monthly online journal club based on three important pillars of neurosurgery - the mechanisms of disease, tools to improve care and clinical trials/policy/global neurosurgery. Each month, an academic trainee will present an academic paper pertaining to one of these pillars, with ample time for discussion. These will be on the first Tuesday of every month at 6pm. Please do sign up to the mailing list via our website (<https://bit.ly/2BHH85I>) and get in touch if you would like to present at one of the sessions!

Anand Pandit, Aswin Chari, Hani Marcus & Professor Rob Brownstone

Dates for your Diary

NANSIG meeting
30th January 2021

SBNS
Spring meeting, Dundee
14th -16th April 2021

BNRG meeting
Cardiff
25th -26th November 2021

Carole Turner
SBNS Research Development and Clinical Trials Manager

Dan Fountain
BNTRC Chair

Michael Jenkinson
SBNS Academic Committee Chair