ECCRG RESEARCH

May 2025

Edinburgh Critical Care Research Group

ECCRG RESEARCH NEWS

Critical Care—Critical Research

Everyday is a school day...

Sitting at the desk thinking about how much we learn every day in research, how much our brain processes this learning, every second of every day—it's continuous. Then thoughts turned to AI to explore how it might express this in a critical care research setting.

Like it or loathe it, AI is here to stay and will influence our future and this is what it came up with…

"In critical care, the notion that 'every day is a school day' resonates deeply. With each patient encounter, every shift and the evolving landscape of medical advancements, the learning never stops. Whether it's adapting to new technologies, clinical skills and processes or trialing new medicine, the critical care environment fosters an atmosphere of continuous education. This mindset encourages healthcare professionals to approach each day with curiosity, humility and a commitment to improvement, ultimately benefiting both staff and patients alike."

It's okay as a short editorial piece—but will AI become more prevalent and indeed necessary in our learning and as it progresses in medicine? A discussion for another issue, but let's look at how our learning is progressing in this one with two new studies!

NIHR Commitment to PPI

This year the National Institute for Health and Care Research have set out 5 new Strategic Commitments for Public Partnerships. This builds on their experience garnered up until 2025 and improve their ambition to be diverse, inclusive and impactful. The commitments reflect widespread engagement and respond to the changing environment for health and care research, harnessing the lived expertise from the patient and public.

The 5 Commitments

1. **Embed research inclusion**
2. **Strengthen partnerships**
3. **Improve reward and recognition**
4. **Require feedback**
5. **Strengthen capacity and capability**

Find out more on their website:

Improving how we partner with patients, carers and the public | NIHR

Inside this issue:

PANGEA— a new commercial study for ICU

We're thrilled to announce our new study which has opened at the Royal Infirmary!

PANGEA is a double-blind, placebo-controlled study assessing the efficacy, tolerability and safety of the drug EU-C-001 in patients with moderate to severe traumatic brain injury. EU-C-001 is a Neurokinin 1 (NK1) antagonist.

The study drug is an experimental treatment for preventing or reversing the development of cerebral swelling, leading to better control of intra cranial pressure (ICP). If the pressure increases this can cause further brain damage or 'secondary injury'. The drug has been shown to restore the blood brain barrier, leading to a return to normal pressure in the brain in animal testing. In healthy human tests, the drug was found to have a good safety profile.

The drug has already shown excellent tolerability in phase 1 testing and the pilot phase of this study is complete. Adults with moderate to severe traumatic brain injury and ICP monitoring in an Intensive Care Unit setting can be recruited within 72 hours of injury.

The study drug or placebo will be given in a blinded fashion into either Group A (study drug) or Group B (placebo). Group A participants will receive 8 x 15 minute infusions, given twice daily over 4 days, under the direction of the research team. Blood sampling for pharmacokinetic and biomarker studies will occur over 5 days, with clinical follow up, up to 12 weeks post injury.

We aim to consent 50 participants to take part in the study over the 10 study centres/hospitals in both the UK and Australia. The research will be conducted over a 3 months period with the majority of procedures occurring over an 8 day period.

Further information is available from Jonathan Rhodes (Principal Investigator), Zoeb Jiwaji, and Scott Simpson (lead ICU research nurse for Neuro).

TBI - Traumatic Brain Injury

ICP—Intra Cranial Pressure

Randomised—Allocating participants to different groups in a research study, without taking any similarities or differences between them into account.

Double Blinded— A type of study in which neither the participant OR their doctors/research team know the randomisation outcome.

Placebo controlled— There are two or more possible allocations. One arm receives treatment, one arm receives placebo (usually saline).

Phase 1—The initial phase of a trial, typically the first time the drug is used on HEALTHY participants.

Pilot phase—A small scale study that is used to prove the viability of the intervention.

Principal Investigator—The Doctor/Nurse responsible for a trial at a local site, who has overview of each patient and trial intervention.

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Declaration of Helsinki—Review October 2024

The World Medical Association (WMA) developed the Declaration of Helsinki (DoH) following the Second World War in 1964, the first ever set of principles guiding medical research involving human participants. The atrocities conducted by physicians during unethical medical research involving humans prompted the design of the guiding principles to direct fundamental ethical considerations and decision making. They still endure today and have just undergone a review, completed in October 2024—60 years after the first version was published. This makes it the 7th revision since inception.

As research and technology has evolved over the decades, the importance of addressing new ethical challenges around the globe is as vital as ever, covering topics such as Artificial Intelligence and big data (analysis of large amounts of data and complex data sets). Tone and language used in research was reviewed and updated, as well as moving away from excluding 'vulnerable' groups so that they may be included in research in a safe and secure way.

In order to have as inclusive, collaborative and transparent approach to the revision as possible, the WMA set up a workgroup in 2022 which was informed by regional and topical meetings over 30 months, across 19 countries. Local and international experts, together with engaged audiences worked together to guarantee diverse opinions. Once this process was complete, the proposed edits were circulated worldwide for two public comment periods to receive feedback.

"... these principles should be upheld by all individuals, teams, and organizations involved in medical research, as [they] are fundamental to respect for and protection of all research participants...."

You can find out more on the WMA website:

Declaration of Helsinki – WMA – The World Medical Association

Dr Jack S Resneck, Chair of the WMA workground for the 2024 revision, was interviewed by The Journal of the American Medical Association (JAMA). Click on the link below to hear his explanation on the relevance of the DoH and why it is revised.

Watch the YouTube video published by the JAMA Network

Test your research skills and meet Arthur on our Case Study

There will be a prize draw!

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WMA WORLD MEDICAL ASSOCIATION

What's happening in the team?

Look who arrived safely!!!

Baby Ruaridh Maydew

Huge congratulations to Jo (Singleton) and Paul who said hello to this happy little chap! Baby Ru arrived on 17th January 2025 and brought with him oodles of love and cuddles.

Welcome to the team Ru – so glad you're helping mum and dad learn all about nappies, milk, sleeping and laundry to add to their already impressive skillbase!

Katie's back!!!

Our lovely research nurse Katie Doverman has returned from maternity leave and we couldn't be more happy to see her!

Katie will be focussing on her beautiful daughter as well as SHORTER, ResultHIP and Intact 2 research studies.

She's also working hard on building a critical care research presence in St John's Hospital.

Katie – it's great to have you back in the research family

Say hi to Polly Black

Polly has been working with the critical care team as a research nurse since the beginning of 2025; focusing her time on the Result-Hip research study each Tuesday. Don't forget to offer her a warm research welcome when you see her on the wards.

Hola
Bonjour
Namaste
Ciao
Hej
Selam

Polly has worked with Emergency Medicine Research Group Edinburgh (EMERGE) for a number of years and more recently as a clinical research fellow with St Andrews University.

We're very happy you joined us Polly!

Front page news! Find out how NIHR are committed to Patient and Public Involvement

DeRISC-3: Coming soon...

Two years ago, we completed a study called DRISC2—now it's time for the sequel!

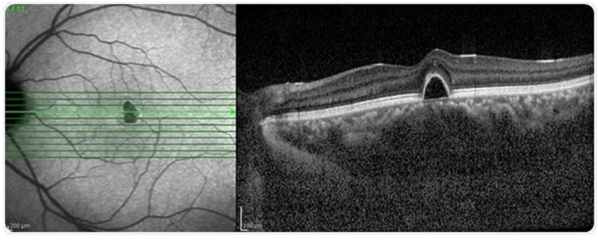
DeRISC-3 involves assessments similar to what might be experienced at the optician—we take some photos of patients eyes using Enhanced Depth Imaging Optical Coherence Tomography (EDI-OCT) to get a clearer look at the blood vessels. We are doing this to gain a better understanding of why patients experience things like confusion/delirium or memory problems during a stay in intensive care. One theory suggests that the brain may be affected due to increased leakage from small blood vessels caused by severe illness. Since the blood vessels in the eye behave similarly to those in the brain, studying and imaging these vessels may provide some insight and eventually lead to new treatments that may enhance brain health and potentially alleviate issues with delirium during a patient's time in intensive care.

You'll see pictures below of what the machine looks like and the type of images we will be collecting. This study is a collaborative effort between the clinical ICU team, the research team and specialists in ophthalmology.

If you see the team in ICU, feel free to stop us to find out more!

What the machine will look like at the bedside

The type of images we'll be examining



What did you learn today? Test your research skills!!

Case Study—Arthur

This is Arthur, a 53 year old man from Edinburgh. He has been in hospital for 5 days with a UTI but has now been admitted to ICU with urosepsis. He's been on antibiotics since admission and had blood cultures taken in ICU. He has a past medical history of Type 2 Diabetes but otherwise healthy. Arthur needs 4l 02 nasal cannula and 12ml/hr of noradrenaline. He is GCS 14 and is mildly confused. The consultant is happy that the research team can enrol him into a study, pending consent.

Q: Which of the 3 studies below do you think Arthur is eligible for?
Bonus Q: Who do you think is appropriate to approach for consent in this situation?

TRAITS:

A trial looking at precision medicine in the treatment of critically ill patients.

Inclusion
* Receiving organ support in ICU
* Organ dysfunction of at least one organ (SOFA>=2)
* Resident in Scotland

Exclusion
* Admitted to ICU more than 48 hours ago
* Primary neurological diagnosis
* Organ Transplantation within 90 days

SOS:

A trial comparing hyperosmolar therapy in traumatic brain injuries.

Inclusion
* Admission to ICU following TBI
* ICP over 20mmHg for more than 5 mins
* <10 days from initial primary injury

Exclusion
* Pregnancy
* Severe Hypernatraemia (sodium >155mmol/L)
* 2 or more prior doses of hyperosmolar therapy already given

SHORTER:

A trial comparing a 5 day course of antibiotics with a course of 7 days or more in the treatment of sepsis.

Inclusion
* Adults treated within ICU setting for suspected or confirmed sepsis
* Evidence of new or worsening acute organ dysfunction from suspected or confirmed infection.
* Antibiotics initiated for confirmed or suspected sepsis and able to be randomised within 4 days of the initiation of this course of antiobiotics

Exclusion
* Comorbidity with immunosuppression (chemo, steroids)
* Receiving end of life care
* The clinician is unable to adhere to the intervention

Which study/ies can Arthur be recruited to ?? Send us an email.

A winner will be picked at random from all correct entries!

Acronym Buster!

AE - Adverse Event
API – Associate Principal Investigator
CI - Chief Investigator
CRF – Clinical Research Facility
Or Case Report Form
GCP – Good Clinical Practice
PerLR – Personal Legal Representative
PI – Principal Investigator
PIS – Patient Information Sheet
PPI – Patient and Public Involvement
ProLR – Professional Legal Representative
REC – Research Ethics committee
SAE - Serious Adverse Event
SUSAR – Suspected Unexpected Serious Adverse Reaction
SIV – Site Investigator Visit

Need to know anything else?
Drop us an email!

More Studies

PANGEA:
A double blinded placebo-controlled study with an open-label pilot phase, assessing the efficacy, tolerability and safety of EU-C-001 in patients with moderate to severe traumatic brain injury.

DeRISC-3:
Delirium Retinal Imaging to Study Cause-3
Taking retinal images to study if blood vessel leakage happens in intensive care patients

Coming Soon...

INTACT-2:
INtravenous iron and eryThropoietin to treat Anaemia following CriTical care

BAC2BAC:
Clinical Validation of Novel Optical Technologies for the Immediate Detection of Respiratory Infection in the Intensive Care

Get In Touch!

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