

PMAS/21/08 - Time critical precision medicine for acute critical illness using treatable trait principles: Data enabled adaptive platform trial with embedded biological characterisation [TRAITS Program].

Our project aims to enable time-critical precision medicine (TCPM) to be used in critically ill patients presenting to emergency departments and Intensive Care Units (ICUs) throughout Scotland. We will develop a collaborative hub based at The University of Edinburgh, to carry out PM Randomised Clinical Trials (RCTs) (supported by data from the NHS). This will mean TCPM can be potentially used at the bedside within 5 years from start of this project.

Precision Medicine (PM) refers to treatments that take individual variability into account. PM is growing in use in cancer care, providing precise treatments for patients based on their genetics or proteins. Currently, it isn't used in ICU because patients admitted to ICU have life threatening illnesses that need treatment immediately and despite current treatment approaches 40% die within 60-days of admission to ICU.

In this project, to enable TCPM in ICU, we have designed a novel clinical trial that will use routinely collected data and test multiple treatments simultaneously. To select patients for this TCPM trial, we will use the results of a blood test done routinely in all patients admitted to ICU needing breathing support, namely low lymphocyte counts.

We plan to assess whether the two lead treatments (recombinant IL-7 and trimodulin) improve survival when administered with usual care. There is preliminary evidence that reversing the effects low lymphocyte count with these two treatments may improve survival in ICU patients.

Consent to participate will be from patients, or their Legal Representative where patients lack capacity. Knowing what happens to participants after they have been recruited is important. Our patient assessments will include short-term outcomes (such as mortality, health related quality of life) and longer-term outcomes such as rehospitalisation. By using routinely collected NHS data to help us understand what happens to patients after they have been discharged from ICU, we will be reducing the burden of trial follow-up for patients.