**RESULT Hip FAQs**

If there are any questions you have which are not covered by this document, please contact the trial team as below:

Sophie Birch – Clinical Coordinator

Tel: 0131 242 3164

RESULT Hip Study Team

Email: RESULTHip.Trial@ed.ac.uk

|  |  |
| --- | --- |
| **GENERAL** | |
| When is the **baseline** day? | Calendar day on which randomisation occurs. |
| What is **day 1**? | The first calendar day after the randomisation (baseline) day.  00:00 – 23:59  \*note, please take bloods 24hrs post baseline bloods. |
| What is the **study day** timeframe? | 00:00 – 23:59 |
| Is RESULT Hip registered on the **NIHR Associate PI** scheme? | Yes.  Can have multiple APIs from different specialties at site as long as PI happy to support. |
| **ELIIBILITY CRITERIA** | |
| **Inclusion:** admitted to acute hospital unit for operative management of hip fracture  Are patients who sustain an inpatient hip fracture eligible for the trial? | Yes |
| **Inclusion:** admitted to acute hospital unit for operative management of hip fracture  The patient I am screening has a pathological hip fracture, are they eligible? | No, they are not eligible to be included. |
| **Inclusion:** admitted to acute hospital unit for operative management of hip fracture  Are patients with a peri-prosthetic fracture able to be included in the study? | No, patients with peri-prosthetic fractures are **NOT** eligible |
| **Randomisation:** presence of anaemia (Haemoglobin equal or less then 90 g.L) at any time from admission until the seven days following surgery  Are patients who have already had a transfusion for clinical reasons in the screening period excluded? | No, patients remain eligible if they have had a transfusion, as long as any post transfusion blood results meet randomisation criteria. |
| **Exclusion**: patient with a new or suspected \* acute coronary syndrome meeting 4th Universal Definition (35) during current admission  Do you have further clarification? | Look out for symptoms of new acute coronary syndrome including: raised troponin; symptoms of myocardial infarction (MI) - e.g. chest pain, etc; ECG changes suggestive of MI (consult with clinical team); Imaging / angiography results ; suggestive of MI (consult with clinical team). Recommend to consult with reviewing clinical team to discuss the above if there are concerns. |
| **Exclusion:** transfusion dependent / chronic anaemias (e.g. Myelodysplasia or bone marrow failure syndromes)\*  If a patient has regular transfusions in the community are they eligible for the study? | No, these patients would not be eligible to participate in RESULT Hip |
| **Exclusion:** transfusion dependent / chronic anaemias (e.g. Myelodysplasia or bone marrow failure syndromes)\*  We are screening a patient who has regular Vitamin B12 injections to manage anaemia, are they excluded from participation? | No, this patient is still eligible to be included.  We are looking at patients who have transfusion dependent chronic anaemias. |
| **SCREENING LOG** | |
| A patient we are screening has long term capacity issues, and does not have an identified consultee who can act on their behalf for consenting purposes.  We are unable to obtain consent, how do we log this on the screening log? | Please mark this patient down as ‘exclusion criteria #2 – unable to consent’ |
| We approached a patient / NoK for the first time when their Hb was 90 or below.  They declined to take part in the study, how do we mark this on the screening log? | Please follow the screening log, and in ‘Has the patient been pre-consented for the trial’ – select no, and the most appropriate reason from the next column.  Continue with the screening log, and record the decline in the ‘reason why patient was not randomised’ |
| We approached a patient / NoK for pre-consent (Hb not 90 or below).  They declined, how do we record this on the screening log?  Do we still need to monitor their Hb to see if it falls? | Please mark the decline in the ‘reason why patient not pre-consented’ column.  In regards to continuing to monitor the patients haemoglobin – as the patient has declined, they have ended their screening period. Please enter the most appropriate response in the ‘presence of anaemia’ column with Hbs collected in the screening period until the patient declined. |
| **INTERVENTION** | |
| **Baseline research blood sample**  A transfusion has been given, do I still take the baseline research blood sample? | Yes, do take a baseline research sample even if a transfusion has been given. Ensure that is noted in the ‘comments’ section of the sample log |
| **Research blood sample**  If baseline blood sample not collected should you do subsequent bloods | Yes. Please try and collect all blood samples as per protocol, even if baseline sample not taken. If samples are not taken please log as a deviation. |
| **Questionnaires – baseline**  How are baseline questionnaires completed if the participant lacks capacity? | Please ask the patients NoK to complete the questionnaires. |
| Transfusion not given within 48hrs | Record as a deviation. This is **not** a violation. |
| **Hb changes** before indicated transfusion given...  Hb = trigger value  ↓  No transfusion is given  ↓  Hb retested within 48hrs of that trigger. This result is no longer a triggering value so no transfusion now required as per protocol. | This is not a deviation.  Latest Hb determines the protocol. NOT a deviation if a repeat Hb is done clinically within the 48 hours before an indicated transfusion, with a result that changes the intervention as per protocol. |
| **When is the patient classed as discharged?** | The day the patient leaves the **acute** hospital, is the discharge date for the study. |
| **30D / 120D Health Care Utilisation Questionnaire** – what if the participant has remained in hospital? | As per guidance on the questionnaire, then only complete Qu 1 & 2.  ‘If you have not left hospital since the 1 month follow up answer questions 1 and 2 only.’ |

\*Changes in yellow included in V4 of protocol (as of 18Jul23 not implemented) but please follow advice