# Clinical Trials Data EGFR - Document 75

# Preoperative Intravenous Iron to Treat Anaemia in Major Surgery

## Clinical Trial: https://clinicaltrials.gov/study/NCT01692418

"eligibilityCriteria": "Inclusion Criteria:\n\n1. At least 18 years of age and signed written informed consent.\n2. Patients undergoing elective major open abdominal surgery.\n\n \* The Indication for operation may be for benign or malignant disease.\n \* Major Surgery is defined as an operation of anticipated duration more than one hour.\n3. Screening haemoglobin (Hb) greater than or equal to 90 g/L (9.0 g/dL) but below or equal to 120 g/L (12.0 g/dL) in women or 130 g/L (13.0 g/dL) in men within four weeks of randomisation.\n4. Randomisation and administration of study infusion a minimum of 10 days and maximum 42 days before planned operation.\n5. Negative pregnancy test for women of childbearing potential (within last 7 days), and agree to use effective form of contraception until 6 weeks post treatment.\n6. Laboratory data used for determination of eligibility at the baseline visit must not be older than four weeks.\n\nExclusion Criteria:\n\n1. Patients undergoing laparoscopic surgery.\n2. Body weight under 50kg.\n3. Known history of acquired iron overload, or family history of haemochromatosis or thalassemia or TSAT \\> 50%.\n4. Known reason for anaemia (e.g. untreated B12 or folate deficiency or haemoglobinopathy).\n5. Known hypersensitivity to ferric carboxymaltose (Ferinject\u00ae) or its excipients.\n6. Temperature \\> 37.5 degrees celsius or patient on non-prophylactic antibiotics\n7. Known chronic liver disease\n8. If clinically indicated for the patient to have LFT's as part of pre-assessment for surgery and this screening alanine transaminase (ALT) or aspartate transaminase (AST) is above three times the upper limit of the normal range.\n9. Received erythropoietin or i.v. iron therapy in the previous 12 weeks.\n10. Immunosuppressive therapy (for organ transplantation) or renal dialysis (current or planned within the next 12 months).\n11. Patients with severe asthma or severe allergy (requiring hospitalisation within the last 12 months).\n12. Unfit for elective surgery.\n13. Pregnancy or lactation.\n14. Inability to fully comprehend and/or perform study procedures in the investigator's opinion.\n15. Patient involvement in another IMP trial within the previous 4 weeks, prior to randomisation. Involvement in another IMP trial, following randomisation, that may impact on the results of the PREVENTT trial.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a EGFR gene mutation be eligible for the clinical trial?

Answer:  
This clinical trial is for patients undergoing major open abdominal surgery. The criteria do \*\*not\*\* mention anything about EGFR gene mutations. Therefore, having an EGFR mutation would \*\*not\*\* automatically exclude a patient, but they would still need to meet all other inclusion and exclusion criteria.