

Project Guidance Document

Clinical Trial Summary

The WHEAT International trial is a comparative effectiveness trial exploring whether withholding enteral feeds around the time of blood transfusion in very premature infants (<30 weeks) will reduce the occurrence of Necrotizing Enterocolitis (NEC). Currently both continued feeding and withholding feeding are approved care practices. The current study will randomize infants from Neonatal Intensive Care Units (NICUs) across Canada and the UK into one of the two care approaches (withholding or continued feeds) to determine if any significant outcomes are found.

Study Arms

WITHHOLDING FEEDS

Baby will have enteral feeds stopped for 10 -12 hours (4 hrs before, during transfusion, 4 hrs after) around the time of all blood transfusions that take place from time of opt-in to 34⁺⁶ weeks.

CONTINUED FEEDS

Baby's feeds will continue as they have been around the time of all blood transfusions that take place from time of opt-in to 34⁺⁶ weeks.

Inclusion Criteria

1. Infant born at less than 30 weeks gestation
2. Infant requiring a blood transfusion

Exclusion Criteria

1. Parent(s) opt out of trial participation
2. Packed red cell transfusion with concurrent enteral feeds prior to enrolment. (Infants who have received a packed red cell transfusion while nil-by-mouth or minimal enteral nutrition (<15 ml/kg/days feeds) are eligible.
3. Infants where enteral feeding is contraindicated in the first 7 days after birth due to a major congenital abnormality of the gastrointestinal tract [GIT].
4. Previous episode of NEC or SIP prior to first packed cell transfusion

Definitions

Feeding – for the purpose of this trial *feeding* is defined as a minimum of 15 ml per kilogram per day

Sepsis – for the purpose of this trial *sepsis* is defined as a confirmed, culture positive case