

Chelwest NNU Thursday am Journal Club

17/03/22

1

Paper of the Week

Efficacy and Safety of Enteral Recombinant Human Insulin in Preterm Infants

Mank et al, 2022
JAMA Pediatrics

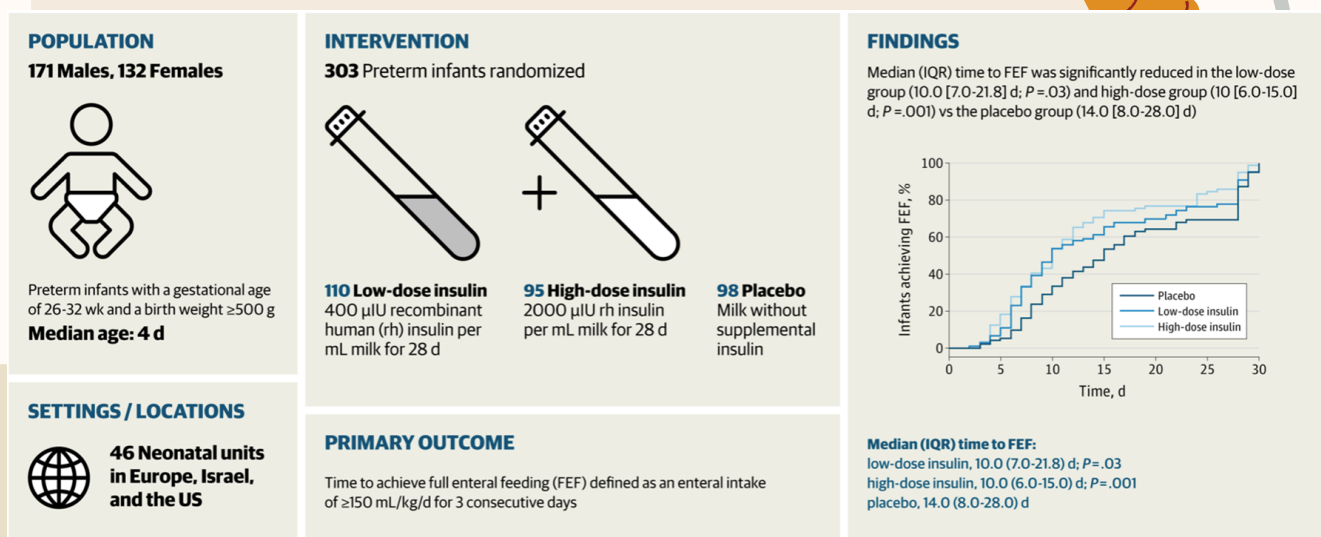
International, multi-centre, double-blind, placebo-controlled RCT



2

Key Question

Does feeding preterm babies insulin decrease the time to reach full enteral feeds?



Mank E, Sáenz de Pipaón M, Lapillonne A, et al; FIT-04 Study Group. Efficacy and safety of enteral recombinant human insulin in preterm infants: a randomized clinical trial. *JAMA Pediatr.* Published online February 28, 2022. doi:10.1001/jamapediatrics.2022.0020

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3

Results

Statistically significant decrease in time to full enteral feeds in both low dose and high dose insulin groups when compared with placebo

Table 2. Efficacy Outcomes (Intention to Treat)

Outcome	Recombinant human insulin		
	Low dose (400- μ U/mL milk)	High dose (2000- μ U/mL milk)	Placebo
Primary outcome			
Time to achieve full enteral feeding (\geq 150 mL/kg/d for 3 consecutive days)			
Total, No.	94	82	85
Median (IQR)	10.0 (7.0 to 21.8)	10.0 (6.0 to 15.0)	14.0 (8.0 to 28.0)
P value ^a	.03	.001	NA
Difference in medians (95% CI) ^b	4.0 (1.0 to 8.0)	4.0 (1.0 to 7.0)	NA

4

Strengths & Limitations

- Clear, focused PICO
- Clear randomisation
- Comprehensive blinding
- Balanced, equally treated study groups
- Clear outcome data with p-values & CIs
- Trial stopped early due to interim futility analysis
- Unclear clinical benefit of primary outcome (does reaching full feeds 1-2 earlier have other benefits?)

Learning Points

Intention to Treat (ITT) = "once randomised, always analysed"! - advantage of reducing bias, replicates the real world & preserves baseline group balance and sample size.

Per Protocol = only includes participants who completed the whole research trial and adhered to all instructions.

Coming up!

Kokul Sriskandarajah presenting on 24/03/22

Any questions/ requests please contact your friendly research fellows at katie.evans7@nhs.net or dominic.carr@nhs.net