

**Title: A HISTORICALLY CONTROLLED COHORT STUDY OF A NOVEL BREAST MILK-BASED HUMAN MILK FORTIFIER IN PRE-TERM INFANTS: EFFECTS ON GROWTH, RESPIRATORY STATUS AND ROP**

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**Background:**

ProlactPlus™ is a breast milk-based HMF (H<sup>2</sup>MF™) containing no cow antigens. The study was to ascertain differences in outcomes such as: growth, NEC, retinopathy of prematurity (ROP), feeding tolerance, and length of stay, of preterm infants who received breast milk fortified with H<sup>2</sup>MF compared to historical controls who received bovine HMF for the first 30 days of fortification.

**Methods:**

Multi-center study of infants born ≤32 weeks GA who received H<sup>2</sup>MF fortified breast milk for 30 days. Subjects were followed until discharge. Start of fortification, supplementation (4-10 cal/oz.) and feeding progression or interruption were ordered by attending MD. Historical controls from the past year were matched for GA, birth weight (BW) and ventilator status at time of enrollment.

Results:

Parameter	Prospective cohort	Historical cohort	p value
GA@ birth - Wks	27 ± 2	27 ± 2	0.71
NICU days: Median ±IQR	78 ± 41.75	75 ±46.75	0.54
Ventilator Days Median ±IQR	15 ±32	38 ±49	0.005
Growth velocity (weight) g/d	20.1 ± 5.2	20.2 ± 4.4	0.92
Growth velocity (length) cm/w	0.70 ±0.28	0.70 ±0.28	0.15
Growth velocity (Head circ.) cm/w	0.63 ± 0.14	0.56 ± .35	0.02
Days of feeding held 2 <sup>o</sup> intolerance Median (Range)	0 (0-11)	0 (0-10)	0.01
NEC incidence (%)	1/66 (1.5)	1/42 (2.4)	1
ROP incidence (%)	2/66(3.0)	10/42 (23.8)	0.0008
ROP incidence ≤ 28 wks GA (%)	2/48 (4.2)	10/35 (28.6)	0.002

**Conclusion:**

Preterm infants receiving H<sup>2</sup>MF grew at rates equal to controls. Although well matched for GA, BW and ventilator use the H<sup>2</sup>MF group required fewer ventilator days. We found that the incidence of ROP was lower in the H<sup>2</sup>MF group. We conclude that H<sup>2</sup>MF promotes growth comparable to that seen with cows milk-based fortifiers and may have a beneficial effect on respiratory status and ROP.