

Web tables and figure

A randomised trial of Granulocyte Macrophage Colony Stimulating Factor for neonatal sepsis: Outcomes at 2 years

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Web Table 1: PROGRAMS: Comparison of infant and maternal characteristics at trial entry and short term outcomes between children who were or were not followed up at 2 years corrected for gestational age

	Followed up (n = 203)		Not followed up (n = 13)		Difference or relative risk (RR)	95% CI for difference or RR
	n or median	% or IQR	n or median	% or IQR		
Characteristics at trial entry						
Male, n (%)	96	47%	6	46%	1.0	0.6 to 1.9
Age at recruitment, h, median (IQR)	45	26-62	35	20-56	4.5	-7 to 19
Gestational age, weeks, median (IQR)	29	27-30	30	27-31	-0.6	-1.6 to 0.4
Birthweight, g, median (IQR)	815	650-930	885	785-1090	-120	-230 to 10
Neutrophil count at trial entry, x10 ⁹ /L, median (IQR)	2.7	1.3-4.2	2.2	1.3-5.3	0	-1.2 to 1.2
Neutropaenia (<1.1x10 ⁹ /L) at trial entry, n (%)	34/194	18%	1/12	8%	2.1	0.3 to 14.1
Multiple pregnancies, n (%)	49/203	24%	4/13	31%	0.8	0.3 to 1.8
Maternal antenatal steroids administered 4 h or more before delivery, n (%)	163/175	93%	11/11	100%	-	-
Infants given surfactant within 4 h of birth, n (%)	146/161	91%	6/7	86%	1.1	0.8 to 1.4
Cranial ultrasound findings at trial entry						
Normal	158/197	80%	12/13	92%		
Minor abnormality	33/197	17%	0/13	0%		
Severe abnormality	6/197	3%	1/13	8%		
Short term outcomes						
Necrotising enterocolitis (confirmed at surgery or post mortem)	6	3%	0	0%	-	-
Sepsis: culture positive to day 28 from trial entry	48	24%	3	23%	1.0	0.4 to 2.8
Sepsis: culture positive and probable to day 28	63	31%	5	38%	0.8	0.4 to 1.7
Cranial ultrasound findings						
Normal	131/173	76%	8/10	80%		
Minor abnormality	28/173	16%	2/10	20%		
Severe abnormality	14/173	8%	0/10	0%		
Oxygen dependency at day 28, n (%)	126	62%	5	38%	1.6	0.8 to 3.2
Oxygen dependency at 36 weeks PMA, n (%)	97	48%	3	23%	2.1	0.8 to 5.6

For categorical variables summary measures are number, %, relative risk and 95% confidence interval (CI). For continuous variables summary measures are median, interquartile range (IQR), difference and 95% CI. The denominator is the entire population, unless otherwise stated, where data were missing.

Web Table 2: Comparison of socio-demographic information at 2 years of age corrected for prematurity in PROGRAMS groups. Denominator indicates the number of children for whom questionnaires were returned

Variable	GM-CSF (n = 72) n (%) or mean (sd)	Control (n = 75) n (%). or mean (sd)
<u>Marital status</u>		
Married	49/71 (69)	46 (61)
Living with partner	13/71 (18)	19 (26)
Single	9/71 (13)	10 (13)
Biological parents at home	59/70 (84)	62/74 (84)
<u>Housing</u>		
Home owner	41/56 (73)	45/59 (76)
Rooms in home, median (IQR)	5 (3 – 6)	5 (3 – 6)
Use of telephone	66/71 (93)	72 (96)
Use of car	61/71 (86)	64 (86)
<u>Mother's qualifications</u>		
O Level/GCSE/equivalent or lesser*	36/71 (51)	30 (41)
<u>Parental employment status</u>		
Mother working	33/69 (48)	36 (48)
Mother in full time education	0/71 (0)	2 (3)
Mother not working	36/71 (51)	37 (49)
Father working	57 (79)	62 (83)
Index of multiple deprivation (2007) † median (IQR) percentile)	n = 60 19 (10-33)	n = 55 17 (10-33)

Notes:

† Based on postcode, Includes only children resident in England

* Maximum qualifications for school leaver at age 16

Web figure 1: Cost-effectiveness plane, expressed in terms of incremental costs and incremental severe disability-free survival

