Supplementary online content

Supplemental material

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Arch Dis Child Fetal Neonatal Ed

eTable 1. Demographics and neonatal characteristics according to treatment group*

	Therapeutic hypothermia (n=25)	Standard care (n=25)	Total (n=50)
Inborn, n/N (%)	13/25 (52.0)	17/25 (68.0)	30/50 (60.0)
Male gender, n/N (%)	17/25 (68.0)	16/25 (64.0)	33/50 (66.0)
Gestational age (weeks), mean (SD)†	39.1 (1.3)	39.2 (1.4)	39.1 (1.3)
Birth weight (g), mean (SD)	2911 (483)	2960 (553)	2935 (515)
Small for gestational age, n/N (%)‡	7/25 (28.0)	7/23 (30.4)	14/48 (29.2)
5-min Apgar score, n/N (%)			
0-3	5/22 (22.7)	1/21 (4.8)	6/43 (14.0)
4-6	13/22 (59.1)	12/21 (57.1)	25/43 (58.1)
7-10	4/22 (18.2)	8/21 (38.1)	12/43 (27.9)
Cord/blood<60min pH, mean (SD)§	6.81 (0.12)	6.93 (0.18)	6.89 (0.17)
Cord/blood <60min base excess, mean (SD)¶	-19.6 (3.2)	-16.5 (4.6)	-17.7 (4.4)
HIE stage at randomisation, n/N (%)			
Moderate	24/25 (96.0)	24/25 (96.0)	48/50 (96.0)
Severe	1/25 (4.0)	1/25 (4.0)	2/50 (4.0)
Thompson score, median (IQR)			
At randomisation	9 (8-10)	9 (8.5-12)	9 (8-11)
Day 7/at discharge**	2 (1-3.25)	2 (2-3.25)	2 (2-3)
Injury pattern on MRI, n/N (%)			
Normal	4/23 (17.4)	2/23 (8.7)	6/46 (13.0)
Only mild/moderate WM injury	4/23 (17.4)	5/23 (21.7)	9/46 (19.6)
Only severe WM injury	0	1/23 (4.3)	1/46 (2.2)
Mild BGT, no/mild/moderate WM injury	13/23 (56.5)	6/23 (26.1)	19/46 (41.3)
Mild BGT, severe WM injury	1/23 (4.3)	0	1/46 (2.2)
Moderate BGT, any WM injury	1/23 (4.3)	5/23 (21.7)	6/46 (13.0)
Global	0	4/23 (17.4)	4/46 (8.7)

*Percentages are based on the number of infants for whom data were available. HIE, hypoxic-ischaemic encephalopathy; WM, white matter; BGT, basal ganglia and thalami.

†Data were unavailable for two infants in the standard care group.

‡Small for gestational age defined as birth weight less than the 10th percentile according to the Intergrowth 21st chart.

§Data were unavailable for 13 infants in therapeutic hypothermia group and seven in standard care group. Cord pH was not available in outborn infants.

¶Data were unavailable for 14 infants in therapeutic hypothermia group and eight in standard care group. Cord base excess was not available in outborn infants.

**Data were unavailable for three infants in therapeutic hypothermia group (two died) and seven in standard care group (five died).

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eTable 2. General movements assessment and outcomes according to treatment group*

	Therapeutic hypothermia (n=25)	Standard care (n=25)	Total (n=50)	P value
Fidgety movements				
Absent (-)	3/21 (14.3)	6/18 (33.3)	9/39 (23.1)	0.255†
Sporadic (+/-)	4/21 (19.0)	6/18 (33.3)	10/39 (25.6)	
Intermittent (+)	12/21 (57.1)	6/18 (33.3)	18/39 (46.2)	
Continual (++)	1/21 (4.8)	0	1/39 (2.6)	
Exaggerated	1/21 (4.8)	0	1/39 (2.6)	
Adverse outcome‡	5/24 (20.8)	12/23 (52.2)	17/47 (36.2)	0.025
Death	2/24 (8.3)	6/23 (26.1)	8/47 (17.0)	0.105
Bayley-III cognitive composite score				0.019
<70	0	3/16 (18.8)	3/38 (7.9)	
70-84	2/22 (9.1)	3/16 (18.8)	5/38 (13.2)	
≥85	20/22 (90.9)	10/16 (62.5)	30/38 (78.9)	
Bayley-III motor composite score				0.074
<70	0	3/16 (18.8)	3/38 (7.9)	
70-84	2/22 (9.1)	1/16 (6.3)	3/38 (7.9)	
≥85	20/22 (90.9)	12/16 (75.0)	32/38 (84.2)	
Cerebral palsy	1/22 (4.5)	3/16 (18.8)	4/38 (10.5)	0.159
GMFCS				
Level 1	1/22 (4.5)	1/16 (6.3)	2/38 (5.3)	
Level 5	0	2/16 (12.5)	2/38 (5.3)	

*Percentages are based on the number of infants for whom data were available. Bayley-III, Bayley Scales of Infant and Toddler Development, third edition; GMFCS, gross motor function classification system.

†P value based on Fisher exact test on absent versus present fidgety movements.

‡Adverse outcome defined as death, cerebral palsy with GMFCS level 3-5 or Bayley-III cognitive and/or motor composite score <85.

eTable 3. Normal/mildly abnormal MRI[*] with adverse outcome[**]

No	Rando-misation	BGT	PLIC	WM	Fidgety movements	Bayley-III cognitive CS	Bayley-III motor CS	CP
1	Non-cooled	Mild	Normal	Normal	Absent	80	79	No
2	Cooled	Normal	Normal	Moderate	Intermittent	100	76	No
3	Cooled	Mild	Equivocal	Moderate	Intermittent	80	70	No
4	Cooled	Mild	Equivocal	Normal	Intermittent	80	89	No
5	Non-cooled	Mild	Normal	Moderate	Sporadic	80	118	No

BGT, basal ganglia and thalami; PLIC, posterior limb of the internal capsule; WM, white matter; Bayley-III, Bayley Scales of Infant and Toddler Development, third edition; CS, composite score; CP, cerebral palsy.
[*]Normal/mildly abnormal MRI defined as normal/mild BGT score and/or normal/mild/moderate WM score.
[**]Adverse outcome defined as death, cerebral palsy with gross motor function classification system (GMFCS) level 3-5 or Bayley-III cognitive and/or motor composite score <85.

eTable 4. Moderately/severely abnormal MRI[*] and/or absent fidgety movements with normal outcome**

No	Rando-misation	BGT	PLIC	WM	Fidgety movements	Bayley-III cognitive CS	Bayley-III motor CS	CP
6	Cooled	Normal	Normal	Mild	Absent	90	112	No
7	Cooled	Mild	Normal	Mild	Absent	95	91	No
8	Cooled	Mild	Normal	Severe	Intermittent	95	100	No
9	Non-cooled	Normal	Normal	Severe	Intermittent	100	115	No
10	Cooled	Moderate	Equivocal	Normal	Absent	100	118	No

BGT, basal ganglia and thalami; PLIC, posterior limb of the internal capsule; WM, white matter; Bayley-III, Bayley Scales of Infant and Toddler Development, third edition; CS, composite score; CP, cerebral palsy.
[*]Moderately/severely abnormal MRI defined as moderate/severe BGT score and/or absent PLIC and/or severe WM score.
[**]Normal outcome defined as survival without cerebral palsy with gross motor function classification system (GMFCS) level 3-5 or Bayley-III cognitive and/or motor composite score <85.