Table A: Baseline clinical and demographic characteristics

	Prednisolone (n=125)	Tetracosactide Depot (n=56)	**Hormonal Alone (n=181)**	Prednisolone with vigabatrin (n=133)	Tetracosactide Depot with vigabatrin (n=48)	**Hormonal with vigabatrin (n=181)**
Sex						
Female	48 (38%)	25 (45%)	**73 (40%)**	58 (44%)	26 (54%)	**84 (46%)**
Male	77 (62%)	31 (55%)	**108 (60%)**	75 (56%)	22 (46%)	**97 (54%)**
Age at randomisation In days						
60-119	5 (4%)	2 (4%)	**7 (4%)**	9 (7%)	7 (15%)	**16 (9%)**
120-179	38 (30%)	16 (29%)	**54 (30%)**	29 (22%)	11 (23%)	**40 (22%)**
180-239	37 (30%)	23 (41%)	**60 (33%)**	51 (38%)	18 (38%)	**69 (38%)**
>=240	45 (36%)	15 (27%)	**60 (33%)**	44 (33%)	12 (25%)	**56 (31%)**
Lead time to Treatment						
Up to 7 days	40 (32%)	12 (21%)	**52 (29%)**	40 (30%)	12 (25%)	**52 (29%)**
8-14 days	19 (15%)	14 (25%)	**33 (18%)**	21 (16%)	12 (25%)	**33 (18%)**
15-28 days	30 (24%)	12 (21%)	**42 (23%)**	27 (20%)	10 (21%)	**37 (20%)**
29 days to 2 months	12 (10%)	13 (23%)	**25 (14%)**	25 (19%)	8 (17%)	**33 (18%)**
More than 2 months	23 (18%)	5 (9%)	**28 (15%)**	18 (14%)	6 (13%)	**24 (13%)**
Not known	1 (1%)	0	**1 (1%)**	2 (2%)	0	**2 (1%)**
Risk of developmental impairment						
Yes	68 (54%)	29 (52%)	**97 (54%)**	72 (54%)	28 (58%)	**100 (55%)**
No	57 (46%)	27 (48%)	**84 (46%)**	61 (46%)	20 (42%)	**81 (45%)**

Table B

Lead-time to treatment and risk of developmental impairment at randomisation*

Lead-time category	Low risk of developmental impairment	High risk of developmental impairment	**Total**
< 7 days	55 (53%)	49 (47%)	**104**
8-14 days	33 (50%)	33 (50%)	**66**
15-28 days	39 (49%)	40 (51%)	**79**
29 days-2 mos.	21 (36%)	37 (64%)	**58**
> 2 months	16 (31%)	36 (69%)	**52**
Total	**164**	**195**	**359**

χ^2 for trend = 8.3, df (1), p = 0.004

*Lead-time to treatment not recorded in 3 cases

Table C

Univariable associations with developmental outcome at 18 months.

	Mean VABS (SE)	Difference (95% CI)	t	p value
Treatment modality				
Combination	73.9 (1.3)	-1.2 (-4.9 to +2.6)	0.6	0.55
Hormonal	72.7 (1.4)			
Early clinical response				
Responder	79.1 (1.2)	15.9 (12.4 to 19.5)	8.8	< 0.001
Non-responder	63.2 (1.1)			
Developmental impairment				
High risk	63.9 (0.91)	20.7 (17.6 to 23.8)	13.1	< 0.001
Low risk	84.6 (1.3)			
Underlying aetiology				
Identified	66.8 (1.0)	15.7 (12.2 to 19.2)	8.9	< 0.001
Not-identified	82.5 (1.5)			
Epilepsy at 18 months				
Present	60.5 (1.1)	18.4 (14.8 to 22.1)	9.9	< 0.001
Absent	78.9 (1.1)			

VABS = Vineland Adaptive Behaviour Score
SE = Standard Error
CI = Confidence Interval
t = t value

Table D

Lead-time to treatment and epilepsy outcomes at 18 months.

Lead-time Category	No epilepsy	Epilepsy*	No Spasms	Spasms#	No AET	On AET⌘
< 7 days	76 (74%)	27 (26%)	94 (91%)	9 (9%)	66 (64%)	37 (36%)
8-14 days	49 (74%)	17 (26%)	56 (85%)	10 (15%)	43 (65%)	23 (35%)
15-28 days	59 (77%)	18 (23%)	69 (90%)	8 (10%)	41 (53%)	36 (47%)
29 days - 2 months	38 (66%)	20 (34%)	48 (83%)	10 (17%)	28 (48%)	30 (52%)
> 2 months	28 (55%)	23 (45%)	34 (67%)	17 (33%)	23 (45%)	28 (55%)
Total	**250**	**105**	**301**	**54**	**201**	**154**

Lead-time to treatment not recorded in 3 cases and epilepsy outcome not recorded in 4 cases

AET = Anti-epileptic treatment

*χ^2 for trend = 5.2, df = 1, p = 0.023

#χ^2 for trend = 11.6, df = 1, p = 0.0007

⌘χ^2 for trend = 7.21, df = 1, p = 0.007

Table E

Lead-time to treatment and epilepsy outcomes at 18 months in infants at high risk of developmental impairment at randomisation.

Lead-time Category	No epilepsy	Epilepsy	No Spasms	Spasms	No AET	On AET
< 7 days	33 (69%)	15 (31%)	43 (90%)	5 (10%)	28 (58%)	20 (42%)
8-14 days	23 (70%)	10 (30%)	25 (76%)	8 (24%)	19 (58%)	14 (42%)
15-28 days	30 (75%)	10 (25%)	37 (93%)	3 (7%)	17 (43%)	23 (57%)
29 days – 2 months	20 (54%)	17 (46%)	28 (76%)	9 (24%)	12 (32%)	25 (68%)
> 2 months	16 (46%)	19 (54%)	20 (57%)	15 (43%)	12 (34%)	23 (66%)
Total	122	71	153	40	88	105

Table F

Lead-time to treatment and epilepsy outcomes at 18 months in infants at lower risk of developmental impairment at randomisation.

Lead-time Category	No epilepsy	Epilepsy	No Spasms	Spasms	No AET	On AET
< 7 days	43 (78%)	12 (22%)	51 (93%)	4 (7%)	38 (69%)	17 (31%)
8-14 days	26 (79%)	7 (21%)	31 (94%)	2 (6%)	24 (73%)	9 (27%)
15-28 days	29 (78%)	8 (22%)	32 (87%)	5 (13%)	24 (65%)	13 (35%)
29 days – 2 months	18 (86%)	3 (14%)	20 (95%)	1 (5%)	16 (76%)	5 (24%)
> 2 months	12 (75%)	4 (25%)	14 (88%)	2 (12%)	11 (69%)	5 (31%)
Total	128	34	148	14	113	49

Table G

Univariable associations with epilepsy outcome at 18 months*.

	Epilepsy at 18 months	% difference (95% CI)	χ^2 (1df)	p value
Treatment modality				
Combination	54/180 (30%)	0.8% (-8.8 to +10.4)	0.03	0.9
Hormonal	52/178 (29.2%)			
Early clinical response				
Responder	39/229 (17%)	34.9% (24.8 to 45.0)	48.2	< 0.001
Non-responder	67/129 (51.9%)			
Developmental impairment				
High risk	72/195 (36.9%)	16% (6.4 to 25.6)	10.9	0.001
Low risk	34/163 (20.9%)			
Underlying aetiology				
Identified	72/206 (35%)	12.6% (2.8 to 24.4)	6.7	0.01
Not-identified	34/152 (22.4%)			

* epilepsy outcome not recorded in 4 cases
CI = confidence interval
df = degrees of freedom

Table H

Univariable associations with infantile spasm outcome at 18 months*.

	Spasms at 18 months	% difference (95% CI)	X^2 (1 df)	p value
Treatment modality				
Combination	27/180 (15%)	0.7% (-6.9 to + 8.3)	0.04	0.85
Hormonal	28/178 (15.7%)			
Early clinical response				
Responder	16/229 (7%)	23.2% (15.2 to 31.2)	34.3	< 0.001
Non-responder	39/129 (30.2%)			
Developmental impairment				
High risk	41/195 (21%)	12.4% (4.8 to 20.0)	10.6	0.001
Low risk	14/163 (8.6%)			
Underlying aetiology				
Identified	37/206 (18%)	6.2% (- 1.5 to +13.9)	2.5	0.11
Not-identified	18/152 (11.8%)			

* epilepsy outcome not recorded in 4 cases
CI = confidence interval
df = degrees of freedom

Table J

Infantile Spasm Outcome at 18 months

Multivariable logistic regression

Infantile Spasms at 18 months	Number with Infantile Spasms at 18 months	Adjusted Odds Ratio (95% CI)	p value
Treatment modality		1.2 (0.6 to 2.3)	0.56
Combination	27/178		
Hormonal	27/177		
Early Clinical Response		0.2 (0.1 to 0.4)	<0.001
Responder	16/228		
Non-responder	38/127		
Developmental Impairment		1.8 (0.9 to 3.6)	0.10
High Risk	40/193		
Low Risk	14/162		
Hormone Type		0.9 (0.5 to 2.2)	0.95
Prednisolone	40/251		
Tetracosactide	14/104		
Hormone Randomised		0.9 (0.4 to 1.8)	0.75
Yes	18/131		
No	36/224		
Lead-time			
< 7 days	9/103	ref	
8-14 days	10/66	1.8 (0.6 to 4.8)	0.27
15-28 days	8/77	1.2 (0.4 to 3.5)	0.70
29 days-2 months	10/58	1.8 (0.7 to 5.1)	0.25
> 2 months	17/51	3.6 (1.4 to 9.2)	0.008

[Likelihood ratio χ^2 44.85, df (9), $p < 0.0001$]

*Lead-time to treatment not recorded in 3 cases and epilepsy outcome not recorded in 4 cases

Table K

Univariable associations with epilepsy treatment at 18 months*

	AET at 18 months	% difference (95% CI)	χ^2	p value
Treatment modality				
Combination	82/180 (45.6%)	2.9% (-7.5 to + 13.3)	0.30	0.59
Hormonal	76/178 (42.7%)			
Early clinical response				
Responder	69/229 (30.1%)	38.9% (28 to 49.9)	50.5	< 0.001
Non-responder	89/129 (69%)			
Developmental impairment				
High risk	108/195 (55.4%)	24.7% (14.3 to 35.1)	22.0	< 0.001
Low risk	50/163 (30.7%)			
Underlying aetiology				
Identified	110/206 (53.4%)	21.8% (10.3 to 33.3)	16.9	< 0.001
Not-identified	48/152 (31.6%)			

* epilepsy outcome not recorded in 4 cases

AET = Anti-epileptic treatment
CI = confidence interval
df = degrees of freedom

Table L

Epilepsy Treatment Outcome at 18 months

Multivariable logistic regression

On Anti-epileptic Treatment (AET) at 18 months	Number on AET at 18 months	Adjusted Odds Ratio (95% CI)	p value
Treatment modality		1.4 (0.9 to 2.2)	0.19
Combination	79/178		
Hormonal	75/177		
Early Clinical Response		0.2 (0.1 to 0.4)	<0.001
Responder	68/228		
Non-responder	86/127		
Developmental Impairment		2.1 (1.3 to 3.4)	0.002
High Risk	105/193		
Low Risk	49/162		
Hormone Type		1.1 (0.6 to 1.9)	0.80
Prednisolone	111/251		
Tetracosactide	43/104		
Hormone Randomised		0.9 (0.5 to 1.4)	0.58
Yes	54/131		
No	100/224		
Lead-time			
< 7 days	37/103	ref	
8-14 days	23/66	0.8 (0.4 to 1.7)	0.6
15-28 days	36/77	1.6 (0.9 to 3.1)	0.14
29 days-2 months	30/58	1.7 (0.8 to 3.5)	0.16
> 2 months	28/51	1.4 (0.6 to 2.9)	0.43

[Likelihood ratio χ^2 66.81, df (9), $p < 0.0001$]

*Lead-time to treatment not recorded in 3 cases and epilepsy outcome not recorded in 4 cases

Table M: Adverse Reactions up to 18 months

Treatment Group	P		T		H		P&V		T&V		H & V	
	N=131		N=60		N=191		N=135		N=51		N=186	
Specific Adverse Reactions	AR	SAR	AR	SAR	AR	SAR	AR	SAR	AR	SAR	AR	SAR
Allergic rash or anaphylaxis	0	-	1 (2%)	-	1 (1%)	-	0	-	0	-	0	-
Drowsiness	3 (2%)	-	0	-	3 (2%)	-	36(27%)	3	12(24%)	1	48(26%)	4
Endocrine/Metabolic Disturbance	1 (1%)	-	1 (2%)	-	2(1%)	-	1 (1%)	-	0	-	1 (1%)	-
Fluid/Electrolyte disturbance	13(10%)	1	10(17%)	2	23(12%)	3	7(5%)	-	5(10%)	1	12(6%)	1
Gastro-intestinal upset	20(15%)	1	6(10%)	1	26(14%)	2	17(13%)	1	6(12%)	1	23(12%)	2
Hypertonia	3 (2%)	1	6 (10%)	-	9(5%)	1	0	-	3(6%)	1	3 (2%)	1
Hypotonia	8 (6%)	1	0	-	8(4%)	1	4 (3%)	-	3 (6%)	-	7 (4%)	-
Immunosuppression	3 (2%)	2	0	-	3 (2%)	2	3(2%)	2	0	-	3 (2%)	2
Increased appetite	36 (27%)	-	15 (25%)	-	51 (27%)	-	25 (19%)	-	10 (20%)	-	35 (19%)	-
Infection	12(9%)	5	9(15%)	2	21(11%)	7	10(7%)	4	4(8%)	-	14(8%)	4
Irritability	54(41%)	2	21(35%)	1	75(39%)	3	46(34%)	1	16(31%)	1	62(33%)	2
Neuropsychiatric (disturbed sleep)	27(21%)	1	8(13%)	-	35(18%)	1	23(17%)	-	7(14%)	-	30(16%)	-
Varicella zoster (chicken pox)#	4(3%)	1	0	-	4(2%)	1	3(2%)	1	0	-	3(2%)	1
Weight gain	23(18%)	-	11(18%)	-	34(18%)	-	19(14%)	-	9(18%)	-	28(15%)	-
(U) Abnormal eye movements	0	-	0	-	0	-	1(1%)	-	0	-	1(1%)	-
(U) Blood disorder - high platelet count	0	-	0	-	0	-	0	-	1(2%)	-	1(1%)	-
(U) Bradycardia	0	-	0	-	0	-	0	-	1(2%)	-	1(1%)	-
(U) Abnormal breathing pattern	1(1%)	-	0	-	1(1%)	-	0	-	0	-	0	-
(U) High signal in basal ganglia	1(1%)	-	0	-	1(1%)	-	2(1%)	-	1(2%)	-	3(2%)	-
(U) Hypoxic	1(1%)	-	0	-	1(1%)	-	0	-	0	-	0	-
(U) Movement disorder	2(2%)	-	0	-	2(1%)	-	8(6%)	-	7(14%)	3	15(8%)	3
(U) Not focusing	0	-	0	-	0	-	1(1%)	-	0	-	1(1%)	-
(U) Obstructive cardiac hypertrophy	1(1%)	1	0	-	1(1%)	1	0	-	0	-	0	-
(U) Pallor	1(1%)	-	0	-	1(1%)	-	0	-	0	-	0	-
(U) Squinting	1(1%)	-	0	-	1(1%)	-	0	-	0	-	0	-
(U) Sweating	0	-	1(2%)	-	1(1%)	-	1(1%)	-	0	-	1(1%)	-
(U) Tachypnoea	1(1%)	-	0	-	1(1%)	-	0	-	0	-	0	-

Legend for Table M

P = Prednisolone, T = Tetracosactide, H = Hormonal Therapies, P&V = Prednisolone and Vigabatrin, T&V = Tetracosactide and Vigabatrin, H&V = Hormonal therapies and Vigabatrin.

AR = Adverse Reaction, SAR = Serious Adverse Reaction

Epilepsy Surgery

One child in the cohort had epilepsy surgery by the time of the 18-month assessment. This child was male and had a history of perinatal intracerebral haemorrhage and had a right functional hemispherectomy. This child had been randomized to combination therapy and had been a non-responder. At the 18-month assessment the Vineland score was 79 and the child did not have active epilepsy.

Principal Investigators and enrolling clinicians

Principal Investigators who were online to recruit (in bold), additional enrolling clinicians and total cases enrolled per centre for the ICISS study. Other clinicians whilst not enrolling patients did manage them during the trial.

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Dr Munir Hussain (Poole) 4

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Dr Puthuval Sivakumar (Stockton on Tees) 0

Dr Robert Smith (York) 0

Dr Sivaranjini Sriskandan (Southend) 0

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Dr Susi Strozzi (Bern) 3

Dr Geeta Subramanian (Romford) 0

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Dr Jacqueline Taylor (Enfield) 1

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Dr Maybelle Wallis (West Bromwich) 0

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