Figure 2
ICISS CONSORT Flow Diagram
Trial Profile

766 infants assessed for eligibility

389 excluded (reasons for exclusion not recorded)

377 infants enrolled and randomly assigned

191 allocated to hormonal therapy alone
60 Tetracosactide depot,
131 Prednisolone
3 also received vigabatrin
9 incomplete compliance (e.g. did not receive recommended dose)

186 allocated to hormonal therapy and vigabatrin
51 Vigabatrin with Tetracosactide depot
134 Vigabatrin with Prednisolone
1 did not receive allocated intervention (parental change of mind)
10 incomplete compliance (e.g. did not receive recommended dose)

191 analysed (1 case deceased before Day 42 but included in analysis and coded as responder)

186 analysed (1 parental decision to withdraw but included in analysis and coded as non-responder)

10 lost to follow-up at 18 months (1 parental request to withdraw, 5 deceased, 4 couldn’t make contact with the parents)

5 lost to follow-up at 18 months (1 parental request to withdraw, 2 deceased, 2 couldn’t make contact with the parents)

181 analysed

Analysis at Day 42

Analysis at Age 18 mth

181 analysed