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# International Collaborative Infantile Spasms Study

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 06/02/2006 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 03/04/2006 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 24/09/2018 | Nervous System Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

**Study website**
http://www.iciss.org.uk

## Contact information

**Type(s)**
Scientific

**Contact name**
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**Contact details**
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
RD01273

# Study information

## Scientific Title
International Collaborative Infantile Spasms Study

## Acronym
ICISS

## Study objectives
The purpose of the trial is to test the following two primary hypotheses:
1. In infantile spasms (including West syndrome), combined treatment with both hormonal treatment and vigabatrin is superior to hormonal treatment alone in eliminating spasms
2. In infantile spasms (including West syndrome), combined treatment with both hormonal treatment and vigabatrin results in better development at 18 months of age than hormonal treatment alone. This effect may only be seen in those infants with no identified aetiology for their spasms.

Secondary hypotheses in those infants allocated combined treatment compared to those allocated hormonal treatment alone:
1. Time to elimination of spasms will be shorter
2. Developmental outcome at 42 months of age will be better; this effect may only be seen in those infants with no identified aetiology for their spasms
3. Epilepsy outcomes at 18 and 42 months of age will be better
4. Number of infants with elimination of spasms and disappearance of the electroencephalogram (EEG), appearance with which it is associated will be better. Those randomly allocated their hormonal treatment will also be compared as above.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
South West Research Ethics Committee, 20/04/2006, ref: 06/MRE06/21

## Study design
Randomised partial blind controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Treatment

## Participant information sheet
Patient information material can be found on the website at http://www.iciss.org.uk

### Health condition(s) or problem(s) studied
Infantile spasms including West syndrome

### Interventions
Hormonal treatment (either prednisolone or tetracosactide depot) alone versus combination of hormonal treatment and vigabatrin

### Intervention Type
Drug

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
1. Hormonal treatment (either prednisolone or tetracosactide depot) alone 2. Vigabatrin

### Primary outcome measure
1. The main early outcome will be the cessation of spasms
2. The main late outcome will be development at 18 months of age

### Secondary outcome measures
1. Absence of spasms on days 13 and 14
2. Electro-clinical outcome
3. Extended electro-clinical outcome
4. The number of consecutive days free of spasms preceding and including day 14
5. Adverse reactions
6. Epilepsy outcome at 18 months of age
7. Development at 42 months of age
8. Epilepsy outcome at 42 months of age

### Overall study start date
01/06/2006

### Completion date
31/12/2014

## Eligibility

### Key inclusion criteria
The clinical features of infantile spasms confirmed by the consultant in charge or his/her nominated deputy and an EEG that is hypsarhythmic or similar, compatible with the diagnosis of infantile spasms

### Participant type(s)
Patient

### Age group
Neonate

### Sex
Both

### Target number of participants
410

### Key exclusion criteria
1. More than 72 hours has elapsed since the EEG was performed
2. More than 72 hours has elapsed since the clinical features were confirmed
3. Age less than two months or greater than one year and two months
4. A diagnosis or high risk of tuberous sclerosis
5. Known affected parent, previously diagnosed cardiac rhabdomyoma, hypomelanic macules, forehead fibrous plaque, shagreen patch, retinal phakoma or known polycystic kidneys
6. Previous treatment for infantile spasms other than a therapeutic trial of pyridoxine to exclude pyridoxine dependent seizures. Previous treatment for other seizure types is not a reason for exclusion.
7. Previous treatment (within the last 28 days) with vigabatrin or hormonal treatments
8. A contraindication to vigabatrin or hormonal treatments
9. A lethal or potentially lethal condition, other than infantile spasms, with a risk of death before 18 months of age
10. Doubt about the ability of the parents or guardians to know when the spasms stop
11. Unavailable for follow up to 18 months of age
12. Those enrolled in a concurrent trial that is still in the active phase
13. The language ability of the parents or guardians is such that they may not understand what is being requested of them
14. The language ability of the parents or guardians is such that it will not be possible to undertake the Vineland assessment

### Date of first enrolment
01/06/2006

### Date of final enrolment
31/12/2014

## Locations

### Countries of recruitment
England

New Zealand

United Kingdom

### Study participating centre
**Royal United Hospital**
Bath
United Kingdom
BA1 3NG

# Sponsor information

### Organisation
Royal United Hospital Bath NHS Trust (UK)

### Sponsor details
c/o Dr Alistair Taylor
Manager Research and Development
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### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/058x7dy48

# Funder(s)

### Funder type
Government

### Funder Name
Castang Foundation (UK)

### Funder Name
Bath Unit for Research in Paediatrics (BURP) (UK)

### Funder Name
National Health Service (NHS) Research and Development Programme (UK)

# Results and Publications

### Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary
Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results up to day 42 | 01/01/2017 | | Yes | No |
| Results article | results of 18-month follow-up | 01/10/2018 | | Yes | No |