

International Collaborative Infantile Spasms Study

Submission date 06/02/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 03/04/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/09/2018	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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, hypomelanotic 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

United Kingdom

England

New Zealand

Study participating centre

Royal United Hospital

Bath

United Kingdom

BA1 3NG

Sponsor information

Organisation

Royal United Hospital Bath NHS Trust (UK)

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes