

A randomised double blind trial of add-on flunarizine to prevent the cognitive deterioration associated with infantile spasms

Submission date 01/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 01/09/2005	Overall study status Completed	☐ Protocol
Last Edited 08/09/2011	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

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

MCT-53573

Study information

Scientific Title

Study objectives

To determine whether infants and children receiving the Infantile Spasms (IS) standard therapy as well as Flunarizine will have an improved developmental outcome as compared to that of children receiving the same treatment with a placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Hôpital Sainte-Justine, Comité d'éthique de la recherche on the 15th July 2004.

Study design

Randomised double blind trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Infantile Spasms (IS)

Interventions

All infants and children will receive initial IS conventional therapy, consisting of Vigabatrin (VGB) administration (as well as vitamin B6), followed after a two week period by Adrenocorticotrophic Hormone (ACTH - Synacthen) treatment, if no IS cessation or amelioration occurs. Moreover, if the infants or children's IS still do not respond to the latter hormone, they may be treated with Topiramate.

Besides the standard IS treatment, Flunarizine or placebo will be administered from the onset of the study for a total of six months in order to determine its efficacy in preventing or ameliorating the mental deterioration associated with IS. After this time, all treatment will be ceased.

Following cessation of treatment, the neurological and neuro-psychological status of infants and children will still be followed for an additional one and one half year period to determine their long-term response to Flunarizine (and to placebo) and to assess their mental development.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Flunarizine, vigabatrin, synacthen, topiramate

Primary outcome(s)

Intelligence Quotient (IQ) scores are evaluated with Bayley scales at time 0 and 24 months.

Key secondary outcome(s)

1. Autistic behaviour
2. Longitudinal development and pattern of developmental progress in infants and children
3. Occurrence of IS

Completion date

31/03/2006

Eligibility**Key inclusion criteria**

1. Children aged 3 - 18 months, either sex, with new onset infantile spasms
2. Electroencephalogram (EEG) showing hypsarrhythmia or modified hypsarrhythmia
3. Children not receiving treatment for infantile spasms at the time of the initial visit, i.e. vigabatrin or synacthen
4. Parents or legal guardian agree to sign the consent form

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 months

Upper age limit

18 months

Sex

All

Key exclusion criteria

1. Age under 3 months or over 18 months at onset of spasms
2. Degenerative neurological disorder because their relentless course toward a poor outcome regardless of therapeutic interventions would limit the possibility of generalising our findings to all children with infantile spasms
3. Pre-existing medical condition where steroids would be contraindicated
4. Families unable to comply with follow-up visits or agree to informed consent

Date of first enrolment

01/04/2002

Date of final enrolment

31/03/2006

Locations

Countries of recruitment

Canada

Study participating centre

Service de Neurologie

Montréal, Quebec

Canada

H3T 1C5

Sponsor information

Organisation

Hôpital Sainte-Justine (Montréal) (Canada)

ROR

<https://ror.org/01gv74p78>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-53573)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration