ISRCTN36757519 https://doi.org/10.1186/ISRCTN36757519

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

Registration date
01/09/2005

Overall study status
Completed

Last Edited
08/09/2011

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] 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

Contact name
Dr Lionel Carmant

Contact details
Service de Neurologie
Hôpital Sainte-Justine
3175 Chemin de la Côte Ste-Catherine
Montréal, Quebec
Canada
H3T 1C5
+1 514 345 4931 (6106)
lionel.carmant@umontreal.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

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

Overall study start date
01/04/2002

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

Age group
Child

Lower age limit
3 Months

Upper age limit
18 Months

Sex
Both

Target number of participants
80

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)

Sponsor details
3175 chemin Côte Ste-Catherine
Montréal, Quebec
Canada
H3T 1C5

Sponsor type
Not defined

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

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