

New therapeutic approach to Tourette Syndrome in children based on a study of the effectiveness and safety of magnesium and vitamin B6

Submission date 04/09/2008	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 30/09/2008	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 20/07/2009	Condition category Mental and Behavioural Disorders	☐ 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

Clinical Trials Information System (CTIS)

2006-005779-16

Protocol serial number

PI06/90242; 0382/2006; STIII2006

Study information

Scientific Title

New therapeutic approach to Tourette Syndrome in children based on a randomised placebo-controlled double-blind phase IV study of the effectiveness and safety of magnesium and vitamin B6

Study objectives

With respect to placebo treatment, the combination of 0.5 mEq/Kg magnesium and 2 mg/Kg vitamin B6 reduces motor and phonic tics and incapacity in cases of exacerbated Tourette Syndrome (TS) among children aged 7 - 14 years, as measured on the Yale Global Tic Severity Scale (YGTSS).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Andalusian Government Committee for Clinical Trials on the 11th December 2006.

Primary study design

Interventional

Study design

Blinded, randomised clinical trial study, phase IV

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Tourette Syndrome

Interventions

Patients will be randomised to the following medication:

1. Magnesium pidolate 0.5 mEq/Kg/day, divided to be taken twice daily. This should not be taken in conjunction with calcium or dairy products.
2. Pyroxidine alpha-aketoglutarate 2 mg/Kg/day, once daily

The clinical data and the YGTSS score at the onset of the period of exacerbation of the clinical condition (t0) will be noted. The parents/guardians will be informed, and on receipt of their informed consent, the aforementioned medication will be provided. This medication is to be taken orally, at the patient's home, and follow-up will be performed, at the healthcare clinic, at 15 (t1), 30 (t2), 60 (t3) and 90 (t4) days. A positron emission tomography (PET) scan will be performed at the start and end of the experimental period, for 15 patients (applied to the first 15 children in the study in both groups, experimental and control, in t0 and t4). The psychological impact of the treatment on the families concerned will be measured using the Psychological General Well-Being Index (PGWBI).

Intervention Type

Supplement

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Magnesium, vitamin B6

Primary outcome(s)

The clinical diagnosis of TS will be confirmed, and the YGTSS score ascertained, so that the patient may be included in the study and any subsequent fall in the global score recorded (at t0 , t1, t2, t3 and t4).

Key secondary outcome(s)

Metabolic changes in baseline and post-treatment PET will be recorded.

Completion date

30/05/2009

Eligibility**Key inclusion criteria**

1. Aged 7 - 14 years, either sex. This is the age bracket during which the natural course of the illness is most exacerbated. Before the age of 7 years, the tics may not yet have appeared (this generally occurs at the age of 5 - 7 years). After 14 years, symptoms tend to stabilise.
2. Informed consent of the child's parents or guardians, and reasoned agreement with the child
3. Clinical diagnosis of TS, according to Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV) criteria
4. Score of 40 or more on the YGTSS

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

7 Years

Upper age limit

14 Years

Sex

All

Key exclusion criteria

1. Severe attention deficit hyperactivity disorder (ADHD) or obsessive compulsive disorder (OCD), not clinically controlled
2. Autism

- 3. Unrelated depression
- 4. Allergy to acetylsalicylic acid (due to the excipients used)

Date of first enrolment

01/10/2007

Date of final enrolment

30/05/2009

Locations

Countries of recruitment

Spain

Study participating centre

Department of Anaesthesia and Reanimation

Marbella

Spain

29603

Sponsor information

Organisation

The Carlos III Health Institute (Instituto de Salud Carlos III) (Spain)

ROR

<https://ror.org/00ca2c886>

Funder(s)

Funder type

Government

Funder Name

The Carlos III Health Institute (Instituto de Salud Carlos III) (Spain) - Healthcare Research Fund (project no. PI06/90242)

Funder Name

Andalusian Regional Government (Spain) - Health Department (project no. 0382/2006)

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?
Protocol article	protocol	10/03/2009		Yes	No
Other publications	analysis of the adapted YGTSS questionnaire	01/03/2008		Yes	No