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

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| **Submission date**<br>04/09/2008 | **Recruitment status**<br>No longer recruiting | [ ] Prospectively registered<br>[X] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>30/09/2008 | **Overall study status**<br>Completed | |
| **Last Edited**<br>20/07/2009 | **Condition category**<br>Mental and Behavioural Disorders | |

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

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**
2006-005779-16

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
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.

### Study design
Blinded, randomised clinical trial study, phase IV

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied
Tourette Syndrome

### Interventions

Patients will be randomsied 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 measure
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).

### Secondary outcome measures
Metabolic changes in baseline and post-treatment PET will be recorded.

### Overall study start date
01/10/2007

### 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

### Age group
Child

### Lower age limit
7 Years

### Upper age limit
14 Years

### Sex
Both

### Target number of participants
38

### 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
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29603

## Sponsor information

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

### Sponsor details
C/ Sinesio Delgado, 6
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### Sponsor type
Research organisation

### Website
http://www.isciii.es/htdocs/en/index.jsp

### 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 Goverment (Spain) - Health Department (project no. 0382/2006)

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