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Randomized double-blind trial of diamine-oxidase (DAO) food supplement to treat patients with episodic migraine and DAO deficiency

Submission date
08/12/2016

Recruitment status
No longer recruiting

Registration date
15/12/2016

Overall study status
Completed

Last Edited
02/03/2018

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A migraine is a type of headache disorder which involves suffering from recurrent headaches that are moderate to severe. These headaches are usually felt as a throbbing pain on one side of the head and can be coupled with visual disturbances and nausea. The exact cause of migraines are unknown, however many believe it is related to histamine, a chemical produced by the immune system cells which help the body to get rid of something that is triggering an allergy. The breakdown of histamine involved different processes, including use of the enzyme diamine-oxidase (DAO). Low activity of DAO is related to the build-up of histamine in the body, which could cause migraines. The aim of this study is to find out whether treatment with DAO is an effective treatment for migraines.

Who can participate?
Adults who have suffered between four and fourteen migraines a month for at least six months.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are treated with DAO 20 minutes before breakfast, lunch and dinner for a total of one month. Those in the second group are treated with a placebo (dummy drug) 20 minutes before breakfast, lunch and dinner for a total of one month. Throughout the treatment period and for a further month, participants in both groups keep diaries recording the number of migraine attacks, duration of the attacks, intensity and treatment used.

What are the possible benefits and risks of participating?
There are no known benefits or risks involved with participating.

Where is the study run from?
Hospital General de Catalunya (Spain)

When is the study starting and how long is it expected to run for?
February 2011 to January 2013

Who is funding the study?
DR Healthcare (Spain)

Who is the main contact?
Dr Joan Izquierdo
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
MigraDAO 002

Study information

Scientific Title
Double blinded trial, comparative and controlled with placebo, to evaluate the efficiency of supplementation with diamino-oxidase versus placebo in the prophylactic treatment of migraine

Study objectives
Patients with migraine have a low activity of diamino-oxidase, and enzymatic supplementation could improve the symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Hospital General de Catalunya, 10/08/2011, ref: V.1.1julio2011 MIGRADAO-002

Primary study design

Interventional

Study design
Double-blind randomised placebo-controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Patients with migraine and deficit in the activity of the Diamine-oxidase.

Interventions
Participants are randomised to one of two groups using the RANUNI procedure (SAS v. 6.12, SAS Institute, Cary, NC, USA).

Group 1: Participants are treated with 14mg diamine-oxidase 20 minutes before breakfast, lunch and dinner for one month

Group 2: Participants are treated with a placebo 20 minutes before breakfast, lunch and dinner for one month

Participants in both groups are followed up for for one month after the treatment period. During this time, participants record the number of migraine attacks, duration of the attacks, intensity and treatment used.

Intervention Type
Supplement

Primary outcome(s)
1. Hours of headache per month are measured using patient diaries at baseline and after 4 weeks of observation and after 4 weeks of treatment
2. Number of migraine crisis during the month are measured using patient diaries at baseline and after 4 weeks of treatment

Key secondary outcome(s)
1. Intensity of pain measured using a visual analogue scale at baseline and after 4 weeks of treatment
2. Number and type of analgesic used during the month is measured using patient diaries baseline and after 4 weeks of treatment

Completion date
01/01/2013

Eligibility

Key inclusion criteria
1. Age between 18 and 65 years old
2. 4-14 migraine episodes per month for a minimum of six months prior to study initiation

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Beginning of migraines when participant was over 50 years old
2. Other kind of headaches diagnosed in the same patient
3. Possibility of pregnancy
4. Preventive treatment for episodic migraine during three months prior the study

Date of first enrolment
01/08/2011

Date of final enrolment
31/07/2012

Locations

Countries of recruitment
Spain

Study participating centre
Hospital General de Catalunya
Pedro i Pons 1
Sant Cugat del Valles (Barcelona)
Spain
08190

Sponsor information

Organisation
DR Healthcare

Funder(s)

Funder type
Industry

Funder Name
DR Healthcare

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mari Luz Latorre (mariluzlatorreb.edu)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	publication results	01/02/2019		Yes	No