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Effectiveness of the enzyme linked immuno-sorbent assay (ELISA) test for the prevention of migraine

Submission date
04/02/2009

Recruitment status
No longer recruiting

Registration date
13/03/2009

Overall study status
Completed

Last Edited
29/01/2016

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
A migraine is a severe headache felt as a throbbing pain at the front or side of the head. The cause of migraine is still not completely understood and treatment is complicated by the differing symptoms experienced. The most common treatments are drugs, either over the counter or those prescribed by a GP or specialist. Some people find that avoiding certain foods and drinks can reduce the number and/or severity of their migraines. The aim of this study is to find out whether a simple blood test is able to identify foods to which people with migraine may be sensitive, and to test whether eliminating these foods from the diet reduces their migraine symptoms.

Who can participate?
Patients aged 18 to 65 who have migraines

What does the study involve?
Participants undergo a pin prick blood test to detect food intolerances. Participants with a positive test result (that is, they are found to have at least one food intolerance) are randomly allocated to one of two groups, either the True Diet (treatment) or Sham Diet (control) group. Both groups are given a diet sheet and are asked to eliminate all foods on their diet sheet for a period of 12 weeks. The True Diet group are sent a diet sheet with the results of their food intolerance test, while the Sham Diet group are sent a diet sheet of equal difficulty but the foods listed are not the true results of their test. Both groups are asked to follow the diet for 12 weeks, completing a daily diary and questionnaires at various time points. At the end of 12 weeks they are asked to reintroduce in a stepwise fashion the foods which they have been asked to eliminate. They are asked to reintroduce one food at a time on a weekly basis and continue with the food if no migraine occurs. This occurs over a 4-week period with all eliminated foods (if no migraine has occurred) being introduced in the final week. At the end of the study all participants are told which diet group they were allocated to and those in the Sham Diet group are provided with their true diet sheet.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
York Trials Unit, Department of Health Sciences, University of York (UK)

When is the study starting and how long is it expected to run for?
March 2008 to February 2009

Who is funding the study?
University of York (UK)

Who is the main contact?
Prof David Torgerson

Contact information

Type(s)
Scientific

Contact name
Prof David Torgerson

Contact details
York Trials Unit
Department of Health Sciences
Area 4, Seebohm Rowntree Building
University of York
Heslington
York
United Kingdom
YO10 5DD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial of food elimination diet based on the enzyme linked immuno-sorbent assay (ELISA) test for food sensitivity for the prevention of migraine

Study objectives
To assess whether the use of a simple linked immuno-sorbent assay (ELISA) test followed by dietary elimination will reduce migraine symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Governance Committee in the Department of Health Sciences at the University of York, 28/04/2008

Study design
Pragmatic double-blind two-arm randomised controlled single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Migraine

Interventions
Participants with a positive ELISA test (that is they have at least one food intolerance) will be randomised to one of two groups, either the True Diet (treatment) or Sham Diet (control) group. The True Diet group will be sent the results of their test while the Sham Diet group will be sent a diet sheet of equal difficulty but the foods listed will not be the true results of their test. Both dietary change groups are asked to follow the diet for a period of 12 weeks. At the end of 12 weeks they are asked to reintroduce, in a stepwise fashion the foods which they have been asked to eliminate. They will be asked to reintroduce one food at a time on a weekly basis and continue with the food if no migraine occurs. This will occur over a 4-week period with all eliminated foods (if no migraine has occurred) being introduced in the final week. All participants will be given the result of their ELISA test at the end of the study.

Intervention Type
Behavioural

Primary outcome measure

Change in number of headache days over the 12 week period. The Migraine Disability Assessment (MIDAS) Questionnaire will be used for this outcome - "On how many days in the last four weeks did you have a headache? (If a headache lasted more than 1 day, count each day)" at baseline, 4 weeks, 12 weeks and 16 weeks.

Secondary outcome measures
Measured at baseline, 4 weeks, 12 weeks and 16 weeks:
1. Total MIDAS score
2. Six-item Total Headache Impact Test (HIT-6) score
3. Number of migraine days

Overall study start date
25/03/2008

Completion date
14/02/2009

Eligibility

Key inclusion criteria
1. Between the ages of 18 - 65 years, either sex
2. Have had two or more migraine attacks (or four or more headache days) in the previous 4 week period
3. Have no other significant co-existing pathology, e.g. have had or currently suffering from an eating disorder (anorexia nervosa/bulimia nervosa)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
172

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
25/03/2008

Date of final enrolment
14/02/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of York - York Trials Unit
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of York (UK) - York Trials Unit

Sponsor details
Department of Health Sciences
Area 4, Seebohm Rowntree Building
Heslington
York
England
United Kingdom
YO10 5DD

Sponsor type
University/education

Website
http://www.york.ac.uk/

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
University/education

Funder Name

University of York

Alternative Name(s)
The University of York, York, Ebor, Universitas Eboracensis

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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?
Results article	results	11/08/2011		Yes	No