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Amyloid β levels in human red blood cells

Submission date 26/06/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/08/2012	**Overall study status** Completed	
Last Edited 30/06/2017	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Alzheimer's disease is the most common form of dementia. It is associated with the accumulation of amyloid β-peptide (Aβ) in the brain. Besides the brain, several changes have been observed in the blood of dementia patients, such as distortions and rapid aging of red blood cells, and an abnormal accumulation of phospholipid hydroperoxides (PLOOH), a sign of membrane oxidative injury. Aβ has been found to cause oxidative injury to red blood cells, impairing their function (i.e., oxygen delivery to the brain), which may contribute to Alzheimer's disease. However, no extensive study has been undertaken of the presence and distribution of Aβ in red blood cells. The aim of this study is to assess the distribution of Aβ in the red blood cells of young and older people.

Who can participate?
People aged 20-69 with total cholesterol level 200-260mg/dL or LDL-cholesterol level 120-180mg/dL

What does the study involve?
The red blood cells Aβ levels are compared between young and older people and also compared to plasma Aβ levels. In addition, a study was previously conducted to find out whether nutritional supplementation with the antioxidant astaxanthin affects red blood cell PLOOH. Red blood cells obtained from this study also have their Aβ levels measured in order to look to the relationship between red blood cell Aβ and antioxidants/oxidants.

What are the possible benefits and risks of participating?
All participants are likely to benefit from general advice. Those with decreasing PLOOH levels have may gain additional benefit, although the effectiveness of this process has not yet been proved. Potential risks include brief pain when drawing blood. This is likely to be similar to the normal muscle ache that people often get and is likely to go away after a couple of minutes.

Where is the study run from?
Shirogane Exe Clinic and Tohoku University (Japan)

When is the study starting and how long is it expected to run for?
June 2010 to September 2010

Who is funding the study?
Yamaha Motor Co., Ltd (Japan)

Who is the main contact?
Associate Professor Kiyotaka Nakagawa

Contact information

Type(s)
Scientific

Contact name
Prof (Associate) Kiyotaka Nakagawa

Contact details
1-1 Tsutsumidori-Amamiyamachi Aoba-ku Sendai
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HR-2010-YH03

Study information

Scientific Title
Amyloid β levels in human red blood cells: a randomized controlled trial

Study objectives
Therapeutic application of astaxanthin as an Aβ-lowering agent in red blood cells (RBCs) could be considered as a possible anti-dementia agent.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of TES Holdings,17/05/2010, ref: 2010-04

Study design
Randomized double-blind placebo controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Astaxanthin supplementation study

Interventions
1. Higher astaxanthin content group: Ingesting supplement containing 1mg astaxanthin
2. Lower astaxanthin content group: Ingesting supplement containing 3mg astaxanthin
3. Control group: placebo

Total duration of investigation was 12 weeks

Intervention Type
Supplement

Primary outcome measure
1. Biological Antioxidant Potential (BAP) test
2. Determination of Reactive Oxygen Metabolites (d-ROMs) test
Measured at Visit 1: Screening, Visit 2: Week 1, Visit 3: Weeks 4, Visit 4: Weeks 12

Secondary outcome measures
Peroxidized phospholipid measured at Visit 1: Screening, Visit 2: Week 1, Visit 3: Weeks 4, Visit 4: Weeks 12

Overall study start date
01/06/2010

Completion date
30/09/2010

Eligibility

Key inclusion criteria
1. Male and female, aged 20-69
2. Blood Test Value: Total Cholesterol: 200-260mg/dL or low density lipoprotein (LDL)-cholesterol: 120-180mg/dL

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
62

Key exclusion criteria
1. All subjects who are capable to cause serious allergy symptoms to foods and medical drugs
2. They ingest medical drugs or herbal medicines which will affect result of test
3. They continuously ingest foods prepared with astaxanthin during past one month or even today
4. They regularly ingest health foods and beverages which profess similar effects with test foods
5. They drink alcohol more four or more days per week in the past three months
6. They have a history of circulatory disease, nephritis and hepatitis
7. They have digestive disease or have experienced the surgery of the digestive organs (except of surgery of appendicitis)
8. They exceed more than 2.5 of the standard value of Aspartate transaminase (AST), Alanine aminotransferase (ALT) and gamma-glutamyltranspeptidase (γ-GT)
9. They exceed more than 9.0 ml/g of the uric acid
10. They have serious anemia
11. They participate in other clinical trial with human subjects
12. They are judged by the principal investigator to participate in this clinical trial

Date of first enrolment
01/06/2010

Date of final enrolment
30/09/2010

Locations

Countries of recruitment
Japan

Study participating centre
1-1 Tsutsumidori-Amamiyamachi Aoba-ku Sendai
Miyagi
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981-8555

Sponsor information

Organisation
Yamaha Motor Co., Ltd (Japan)

Sponsor details
3001-10 Kuno Fukuroi
Shizuoka
Japan
437-0061

Sponsor type
Industry

ROR
https://ror.org/05s7fvh27

Funder(s)

Funder type
Industry

Funder Name
Yamaha Motor Co., Ltd. (Japan)

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	01/07/2012		Yes	No