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The effect of mercury exposure on inflammation in autoimmune disease

Submission date
05/07/2016

Recruitment status
No longer recruiting

Registration date
04/08/2016

Overall study status
Completed

Last Edited
15/09/2016

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Systemic lupus erythematosus (SLE) is a long-term (chronic) disease which causes widespread inflammation (swelling) in the body. SLE occurs when the immune system attacks the body's own cells (autoimmune disease). A person's genes alongside other factors such as diet have been connected with the development and progression of the disease. As the severity of SLE greatly varies between patients, research has been undertaken to find out how beneficial or detrimental lifestyle factors can be for different patients. There is a lot of evidence that eating oily fish can be beneficial for patients with SLE, as it is rich in n-3 fatty acids (omega 3), which has been shown to decrease inflammation and reduce disease activity in SLE. Whilst fish provide beneficial nutrients to the human diet they also contain tiny amounts of mercury. There is limited research on the effect mercury may have in SLE. Mercury concentrations vary between fish and are largely dictated by the size and species of fish. There is some evidence that benefits of the n-3 fatty acids present in fish that we eat outweighs any negative effects from any mercury also present. The aim of this study is to investigate the effect of mercury and n-3 fatty acids on the production of biomarkers (natural chemical indicators) of inflammation, using blood cells taken from people with SLE and from those without SLE, in order to find out if the n-3 fatty acids will have an anti-inflammatory effect over and above any pro-inflammatory effect that mercury may have on the cells.

Who can participate?
Adults with SLE and healthy adults of the same age and gender.

What does the study involve?
All participants provide a small blood sample. From each sample, the immune cells are removed and treated in the laboratory with docosahexaenoic acid or eicosapentaenoic acid (two types of omega 3) or a vehicle control (dummy solution). After 24 hours, the cells are treated with mercury or a vehicle control (dummy) for another 24 hours. The amount of natural chemical indicators of inflammation produced by the cells are then measured.

What are the possible benefits and risks of participating?
There are no direct benefits involved with participating in this study. There is a small risk of bruising following removal of blood, however researchers conducting this procedure are trained and experienced.

Where is the study run from?
Ulster University (UK)

When is the study starting and how long is it expected to run for?
May 2015 to December 2016

Who is funding the study?
Ulster University (UK)

Who is the main contact?
Dr Emeir McSorley
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1

Study information

Scientific Title
An in vitro study to determine the effect of mercury and n-3 fatty acids on markers of inflammation in systemic lupus erythematosus

Study objectives
Lymphocytes from autoimmune patients exposed to methylmercury will elicit a more pronounced pro-inflammatory effect than lymphocytes from healthy controls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics committees Northern Ireland (ORECNI), 20/05/2015, ref: 15/NI/0062

Study design
Laboratory-based case-control study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Systemic Lupus Erythematosus

Interventions
Twelve Systemic lupus erythematosus participants and twelve age and gender matched controls will be recruited from Northern Ireland and donate a 27mls blood samples.

Peripheral blood mononuclear cells taken from all participants will be pre-treated with docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) or vehicle control. Following incubation for 24 hours, cells will be treated with methyl mercury and LPS or vehicle control for a further 24 hours. Supernatants will be stored at -80 degrees Celsius.

Pro-inflammatory cytokines will be measured in supernatants using a multiplex ELISA.

Intervention Type
Other

Primary outcome(s)
Pro-inflammatory cytokines secreted from peripheral blood mononuclear cells will be measured using a multiplex ELISA assay.

Key secondary outcome(s))
No secondary outcome measures.

Completion date
01/12/2016

Eligibility

Key inclusion criteria
Systemic lupus erythematosus (SLE) participants:
1. Aged between 18-65

2. A diagnosis of SLE (American College of Rheumatology criteria)
3. Not currently pregnant
4. Not currently taking any n-3 fatty acid supplements

Control participants:
1. Aged between 18-65
2. Free from illness
3. Not taking any medication (including non-steroidal anti-inflammatories)
4. Not currently pregnant
5. Not currently taking any n-3 fatty acid supplements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
Systemic lupus erythematosus (SLE) participants:
1. Currently on high dose steroids (>10mg daily)
2. Currently suffering from an acute illness
3. Regularly consume more than 3 portions of fish per week
4. Pregnancy
5. Currently taking any n-3 fatty acid supplements

Control participants:
1. Regularly consume more than 3 portions of fish per week
2. Pregnancy
3. Currently taking any n-3 fatty acid supplements

Date of first enrolment
20/05/2015

Date of final enrolment
31/07/2016

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Ulster University
Cromore Road
Coleraine
United Kingdom
BT52 1SA

Sponsor information

Organisation
Ulster University

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
University/education

Funder Name
Ulster University

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet		02/03/2015	15/09/2016	No	Yes

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes