ISRCTN91649606 https://doi.org/10.1186/ISRCTN91649606

The relationship between mercury and systemic lupus erythematosus

Submission date
08/08/2014

Recruitment status
No longer recruiting

Registration date
22/09/2014

Overall study status
Completed

Last Edited
13/05/2016

Condition category
Musculoskeletal Diseases

[X] 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 an inflammatory condition where the immune system targets the body's own tissues. SLE is thought to arise from interplay between genetic and environmental factors. One such environmental factor that has been proposed is exposure to mercury. This study aims to find the relationship between exposure to mercury and disease activity in people with SLE.

Who can participate?
SLE patients between the age of 18-65 can participate in this study.

What does the study involve?
The patients are required to provide a blood, urine and hair sample as well as being assessed for disease activity and damage. Patients will also complete questionnaires detailing dental history, lifestyle choices and eating habits. This will be for a duration of one year. Each patient will only be assessed on one occasion.

What are the possible benefits and risks of participating?
Information obtained from this study will contribute to the understanding of SLE. There are no foreseen risks to the patient.

Where is the study run from?
The University of Ulster in collaboration with the rheumatology clinics of the National Health Service (NHS) will conduct this research.

When is the study starting and how long is it expected to run for?
November 2014 to November 2016

Who is funding the study?
Northern Ireland Department of Employment and Learning (DEL)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1

Study information

Scientific Title
An investigation of the exposure to inorganic and organic mercury (HG) and its relationship with disease activity in Systemic Lupus Erythematosus

Acronym
HGSLE

Study objectives
It is postulated that there is an association between inorganic and organic mercury exposure and the development and progression of systemic autoimmunity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office of Research Ethic committee Northern Ireland (ORECNI), 09/01/2015. REC Ref: 14/NI/1139

Study design

Cross-sectional study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Systemic lupus erythematosus

Interventions
Patients will be assessed for disease activity and damage, and exposure to inorganic and methyl mercury. Fatty acids will be measured in the blood of the patients. They will have their dental amalgams quantified and will complete a dental history questionnaire as well as a lifestyle and food consumption questionnaires. Recruitment and sampling will be for a duration of one year. Each patient will only be assessed on one occasion.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The primary aim is to investigate the relationship between concentrations of mercury in hair (reflecting organic mercury exposure) and urine (reflecting inorganic mercury exposure) and disease activity in systemic lupus erythematosus patients. These will be assessed at one timepoint for each patient. Hair mercury will be measured using atomic absorption spectrometry. Urinary mercury will be analysed using cold vapour atomic fluorescence spectrometry. Disease activity will be measured using the revised systemic lupus activity measure (SLAM-R), the British Isles Lupus Assessment Group (BILAG), and the Safety of Estrogen in Lupus Erythematosus National Assessment Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI).
Disease-associated damage will be measured using the Systemic Lupus International Collaborative Clinics (SLICC) American College of Rheumatology (ACR) index.

Key secondary outcome(s))
The secondary aims are to investigate if genes related to how an individual absorbs or excretes mercury will have an impact on hair and urinary mercury concentrations and disease activity. Furthermore, this study will investigate if exposure to mercury impacts on markers of inflammation. These will be assessed at one timepoint for each patient. Genotyping will be completed using PCR. Markers of inflammation will be measured using ELISA.

Completion date
01/11/2016

Eligibility

Key inclusion criteria

1. A positive diagnosis of SLE using the American College of Rheumatology (ACR) diagnosis criteria
2. Patients must be aged between 18-65

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
1. Currently pregnant
2. Have ever undergone chelation therapy

Date of first enrolment
10/04/2015

Date of final enrolment
01/09/2016

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Belfast City Hospital
Lisburn Road
United Kingdom
BT9 7AB

Study participating centre

Altnagelvin Area Hospital
Glenshane Road
Londonderry
United Kingdom
BT47 6SB

Sponsor information

Organisation
The Department of Employment and Learning (DEL) (UK)

ROR
https://ror.org/05w9mt194

Funder(s)

Funder type
Government

Funder Name
The Department of Employment and Learning (DEL) (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No