

# The relationship between mercury and systemic lupus erythematosus

<b>Submission date</b> 08/08/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 22/09/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 13/05/2016	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?  
Mr William Crowe  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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BT52 1SA

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Secondary study design**

Cross sectional study

**Study setting(s)**

Other

**Study type(s)**

Screening

**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**

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 measure**

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.

## **Secondary outcome measures**

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.

## **Overall study start date**

01/11/2014

## **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

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Upper age limit**

65 Years

## **Sex**

Both

## **Target number of participants**

172

## **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**

Northern Ireland

United Kingdom

**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)

**Sponsor details**

Adelaide House

39 - 49 Adelaide Street

Belfast

United Kingdom

BT13 3NG

**Sponsor type**

Government

**Website**

<http://www.delni.gov.uk/>

**ROR**

<https://ror.org/05w9mt194>

## **Funder(s)**

**Funder type**  
Government

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

## Results and Publications

**Publication and dissemination plan**  
To be confirmed at a later date

**Intention to publish date**

**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?
<a href="#">HRA research summary</a>			28/06/2023	No	No