# Leicester Sleep and Sugar Study

Submission date Prospectively registered Recruitment status 28/05/2010 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 28/05/2010 Completed [X] Results [ ] Individual participant data Last Edited Condition category 02/04/2020 Nervous System Diseases

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Ms Emer Brady

#### Contact details

Leicester Royal Infirmary Infirmary Square Leicester United Kingdom LE1 5WW

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abc@email.com

## Additional identifiers

EudraCT/CTIS number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers 3783

## Study information

Scientific Title

Leicester Sleep and Sugar Study

#### Acronym

DRN074 (Leicester Sleep and Sugar Study)

#### **Study objectives**

Obstructive sleep apnoea (OSA) is a significant medical problem that affects approximately 4% of middle aged males and approximately 2% of adult females. Previous studies have highlighted the association between OSA and obesity, hypertension, insulin resistance and dyslipidemia, a cluster similar to that seen in the metabolic syndrome (MetS). The MetS itself is a significant risk factor for the development of type 2 diabetes (T2DM), cardiovascular disease (CVD) and cardiovascular mortality.

Sub-clinical systemic inflammation has been consistently observed in patients with T2DM and in those with the MetS. A number of inflammatory mediators, e.g., tumour necrosis factor-alpha (TNF-a), interleukin-6 (IL-6) have shown to be positively correlated with glucose intolerance and sleep deprivation. The association between inflammation and the pathogenesis of diseases such as T2DM, CVD and OSA is currently a pivotal area of research today.

The aim of this pilot study is to further establish the association between inflammatory mediators and poor sleep quality in a multiethnic population. In addition to investigating the positive effect that restoration of sleep has on glycemic control and inflammatory biomarkers that are associated with T2DM, CVD and MetS through continuous positive airway pressure (CPAP) therapy.

#### Ethics approval required

Old ethics approval format

### Ethics approval(s)

MREC approved (ref: 06/Q2501/97)

#### Study design

Single centre non-randomised interventional diagnosis, process of care and treatment trial

## Primary study design

Interventional

## Secondary study design

Non randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

**Treatment** 

#### Participant information sheet

## Health condition(s) or problem(s) studied

Topic: Diabetes Research Network; Subtopic: Type 2; Disease: Cardiovascular disease, Multiple complications

#### **Interventions**

To measure the effect that sleep restoration (via CPAP) has on glucose tolerance and inflammation based on change in HBA1c levels and change in the level of recognised inflammatory biomarkers.

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome measure

Participant HBA1c levels

#### Secondary outcome measures

- 1. Participant plasma levels of recognised inflammatory biomarkers
- 2. Participant compliance with CPAP
- 3. Participant Epworth Sleepiness Scale (ESS), Hospital Anxiety and Depression Scale (HADS) and Quality of Life (QoL) scores
- 4. Participant glycaemic control via capillary blood glucose monitoring (CBGM) results
- 5. Participant insulin sensitivity via homeostasis model assessmentinsulin resistance (HOMA-IR) analysis

#### Overall study start date

29/11/2006

#### Completion date

18/04/2008

## **Eligibility**

#### Key inclusion criteria

- 1. Body mass index (BMI) greater than or equal to 35 kg/m^2
- 2. Established type 2 diabetes (greater than 3 months)
- 3. Undiagnosed obstructive sleep apnoea

#### Participant type(s)

Patient

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

#### Target number of participants

Planned sample size: 50; UK sample size: 50

#### Key exclusion criteria

- 1. BMI less than 35 kg/m^2
- 2. Diagnosed with type 2 diabetes within last 3 months
- 3. Diagnosis of obstructive sleep apnoea

#### Date of first enrolment

29/11/2006

#### Date of final enrolment

18/04/2008

## Locations

## Countries of recruitment

England

**United Kingdom** 

## Study participating centre Leicester Royal Infirmary

Leicester United Kingdom LE1 5WW

## **Sponsor information**

## Organisation

University Hospitals of Leicester NHS Trust (UK)

#### Sponsor details

Leicester Royal Infirmary Infirmary Square Leicester England United Kingdom LE1 5WW

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.uhl-tr.nhs.uk/

#### **ROR**

https://ror.org/02fha3693

# Funder(s)

## Funder type

Research council

#### Funder Name

Biotechnology and Biological Science Research Council (BBSRC) (UK) (ref: PJMRM62078)

## **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 in PhD thesis at		02/04/2020	Yes	No