

Leicester Sleep and Sugar Study

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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)

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

Participant HBA1c levels

Key secondary outcome(s)

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 assessment/insulin resistance (HOMA-IR) analysis

Completion date

18/04/2008

Eligibility

Key inclusion criteria

1. Body mass index (BMI) greater than or equal to 35 kg/m²
2. Established type 2 diabetes (greater than 3 months)
3. Undiagnosed obstructive sleep apnoea

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. BMI less than 35 kg/m²
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

United Kingdom

England

Study participating centre
Leicester Royal Infirmary
Leicester
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LE1 5WW

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (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

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