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Leicester Sleep and Sugar Study

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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England
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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