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Investigating sleepiness in the HIV population in UK

Submission date
27/02/2018

Recruitment status
No longer recruiting

Registration date
30/04/2018

Overall study status
Completed

Last Edited
22/11/2018

Condition category
Infections and Infestations

[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
Excessive daytime sleepiness describes the feeling of constant tiredness and an increased likelihood of falling asleep, even when not intending to. This is associated with an adverse effect on quality of life and functionality and an increased risk of car and workplace accidents. Previous research has indicated that this problem is very common people living with HIV with up to 40% of people affected. Less is known about why this is, with possible causes including bad sleep habits, insomnia, depression, medication and drug side effects, and sleep disorders including obstructive sleep apnoea (OSA), a condition where episodic closures of the upper airway during sleep lead to multiple night time awakenings and unrefreshing sleep. It is estimated that OSA is undiagnosed in up to 85% of cases in the general population and therefore may be responsible for some of the burden of sleepiness symptoms in people living with HIV.
The aims of this study are to estimate how common excessive daytime sleepiness is in the outpatient HIV population at the Royal Free Hospital using questionnaires, to do tests on those who are excessively sleepy to find out how many have OSA, and to treat those with OSA and see the effect on symptoms.

Who can participate?
People aged over 18 living with HIV attending outpatients at the Royal Free Hospital, London

What does the study involve?
The study has three parts. In Part 1 participants are asked to complete questionnaires asking about aspects of sleep and related medical history, lifestyle factors and symptoms. In Part 2 those identified to have excessive daytime sleepiness undergo a home sleep study, a routine clinical test used to identify evidence of obstructive sleep apnoea. In Part 3 those found to have obstructive sleep apnoea are offered treatment with continuous positive pressure therapy (CPAP), the gold standard treatment. This is a tight fitting mask that blows air in to the upper airway open to keep it open and prevent sleep disruption. The researchers then measure the effect of this on symptoms

What are the possible benefits and risks of participating?
The study will address a group of symptoms that are not always asked about in routine clinical consultations (sleep health, depression, anxiety). Those with high symptom scores of depression

and anxiety will be offered referral to the clinical psychology team. Those with obstructive sleep apnoea will be identified and offered treatment which should improve their symptoms of sleepiness and reduce their long-term health risk. The study will also raise awareness about sleep and related health in the HIV population. No significant risks are expected as it is non-interventional and just a questionnaire and then observing routine clinical tests and treatment. The majority of participants will only be completing a questionnaire and hence the burden on their time is not significant.

When is the study starting and how long is it expected to run for?
May 2018 to August 2019

Who is funding the study?
Royal Free Charity (UK)

Who is the main contact?
Dr Amina Jaffer

Contact information

Type(s)
Public

Contact name
Dr Amina Jaffer

Contact details
Department of Respiratory Medicine
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Additional identifiers

Protocol serial number
11474

Study information

Scientific Title
Obstructive sleep apnoea syndrome in people living with HIV: how common is this, and can we effectively treat those who are affected?

Study objectives
1. Excessive daytime somnolence is responsible for a significant symptom burden in people living with HIV
2. A proportion of people living with HIV with daytime somnolence have undiagnosed and hence untreated obstructive sleep apnoea syndrome
3. Treating moderate to severe OSA in PLWH with excessive sleepiness will lead to a reduction in sleepiness and an improvement in overall health related quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West- Cornwall & Plymouth Research Ethics Committee, ref: 18/SW/0084

Study design
Single-centre observational pilot and feasibility study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Excessive daytime sleepiness in people living with HIV

Interventions
The study is in three parts with a total duration of 15 months:

Part 1: The trialists will be performing a questionnaire on 325 participants (a representative sample of the outpatient HIV population at the Royal Free Hospital). The questionnaires will be organised into a booklet that should take a maximum of 20 minutes to complete. This questionnaire booklet which will include the following clinical questionnaires:
• Epworth Sleepiness Scale (measures how sleepy a person is with a score >10 indicating excessive daytime sleepiness)
• Fatigue Severity Scale (measures severity of fatigue experienced)
• PHQ-9 (measures symptoms of depression)
• GAD-7 (measures symptoms of anxiety)
• EuroQOL 5D 5L (measures overall health related quality of life)
• Pittsburgh Sleep Quality Index (measures aspects of sleep quality)
• Promis Sleep quality and Sleep related impairment short forms (measure aspects of sleep quality and the effect of sleep on activities of daily living)

Part 2: In those identified to have excessive sleepiness (Epworth score >10, estimated to be 100 patients)) the trialists will perform overnight oximetry to identify how many have obstructive sleep apnoea.

Part 3: Those identified to have obstructive sleep apnoea will be offered treatment with continuous positive pressure therapy (CPAP), the gold standard treatment. The trialists will observe their adherence to CPAP therapy and measure their symptom scores (repeat of initial questionnaire) at 6 and 12 weeks after starting treatment.

Intervention Type
Other

Primary outcome(s)
Estimated prevalence of obstructive sleep apnoea syndrome (OSAS, obstructive sleep apnoea with excessive daytime sleepiness) in the outpatient HIV population attending the Royal Free

Hospital. This is a derived value obtained by a two-step analysis.
1. Using a representative sample of 325 patients, the number of participants with excessive daytime sleepiness as measured by an Epworth Sleepiness Scale score (ESS) >10
2. Using sleep study data on the participants with ESS >10, the number of participants with obstructive sleep apnoea (OSA), classified as AHI 5-15 (mild OSA), AHI 15-30 (moderate OSA) and ESS >30 (severe OSA). The total number of participants with proven OSA in the sleep study will be utilised as a percentage of the total number sampled to estimate a prevalence of OSAS in the outpatient HIV population

Key secondary outcome(s))
1. The sample population scores on other symptom and behaviour based questionnaires (FSS, PSQI, GAD-7, PHQ-9, EuroQOL 5D 5L) and the correlation of these with reported sleepiness score on ESS
2. Adherence and hours of use of CPAP in HIV-positive patients with proven moderate to severe OSA
3. AHI on treatment as recorded by the CPAP machines and comparison to pre-treatment values
4. The change in symptom scores pre- and post- CPAP treatment (ESS, FSS, GAD-7, PHQ-9, EuroQOL 5D 5L) in HIV-positive participants with proven moderate to severe OSA

Completion date
01/08/2019

Eligibility

Key inclusion criteria
Part 1 (questionnaire study):
1. HIV positive patient attending outpatient appointment at Royal Free Hospital
2. Informed consent to participate in study
3. Aged >18

Part 2 (investigating participants with excessive daytime sleepiness):
1. As per part 1 plus Epworth Sleepiness Scale score >10

Part 3 (evaluating CPAP treatment in those found to have obstructive sleep apnoea):
1. As per Part 1 and 2 plus Positive sleep study for evidence of obstructive sleep apnoea with Apnoea Hypopnoea Index ≥15

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Key exclusion criteria
Part 1:
1. Aged <18
2. Consent not given to participate in study
3. Unable to participate for the duration of the study

Part 2:
1. As per above (Part 1) plus Epworth sleepiness score ≤10
2. Pregnancy
3. Socioeconomic factors such as no fixed abode making regular outpatient attendance and communication too challenging

Part 3:
As per Part 2 and 3 plus:
1. AHI <5 on sleep study
2. Physical disability such as previous stroke that renders the patient unable to use CPAP treatment

Date of first enrolment
01/05/2018

Date of final enrolment
31/01/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
Royal Free London NHS Foundation Trust

ROR

https://ror.org/04rtdp853

Funder(s)

Funder type
Charity

Funder Name
Royal Free Charity

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes