

Prevalence and treatment of sleep-disordered breathing in Down's syndrome

Submission date 20/12/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 03/02/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/10/2022	Condition category Respiratory	☐ 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
1

Study information

Scientific Title
Controlled prospective trial of the effectiveness of continuous positive airway pressure therapy in adults with Down's syndrome

Study objectives

Continuous positive airway pressure (CPAP) use in Down's syndrome (DS) adults with obstructive sleep apnoea/hypopnoea syndrome (OSAHS)/sleep-disordered breathing (SDB) improves sleepiness and quality of life more effectively than lifestyle measures alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Scotland A Research Ethics Committee, 28/02/2011 and substantial amendment on 17/05/2011, ref: 11/MRE00/3

Primary study design

Interventional

Study design

Repeated measures parallel-arm controlled intention to treat study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Sleep disordered breathing, obstructive sleep apnoea, Down's syndrome

Interventions

All participants with a diagnosis of sleep apnoea on home sleep study will be randomised to either the Lifestyle group or the CPAP Group. Participants allocated to the Lifestyle Group will receive written lifestyle advice on diet, exercise, sleep hygiene and sleeping position. Participants allocated to the CPAP Group will receive CPAP at the optimal pressure to treat their symptoms, along with written lifestyle advice as per the Lifestyle Group. Participants in both groups will be followed up at 1 week & at 1 month after randomisation. After 1 month, the Lifestyle Group will be offered CPAP, with additional follow ups at 1 week and 1 month after commencing CPAP. Both groups will then be followed at 3 months and 6 months after randomisation. At 6 months, participation in the study is complete, and all participants will be encouraged to remain on CPAP.

Participants in both limbs will have anthropometric measures, cognitive function tests, health questionnaires, carer questionnaires and documentation of healthcare contact at baseline (randomisation), 1 month, 3 months & 6 months. All participants will complete and return a monthly diary recording health care contact, caffeine intake, medication, health questionnaires and a carer questionnaire.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Change in Subjective Sleepiness: Epworth Sleepiness Scale (ESS) recorded at baseline, 1 week and monthly thereafter (averaged over 1, 3, and 6 months).

2. Change in health related quality of life: EQ-5D (measured at baseline, 1, 3 and 6 months) valued using UK population tariffs. This will be used to estimate the cost per quality-adjusted life year (QALY) gained by providing CPAP in comparison to lifestyle measures. The analysis will incorporate health care utilisation, including hospital visits and GP visits during the trial (recorded by monthly diary) and 3 months prior to trial entry (obtained via GP letter and review of patient records).

Key secondary outcome(s)

1. Objective changes in emotional and behavioural function: Modified DBC-A - measured at baseline and monthly thereafter
2. Health status (quality of life): SF-12, SAQLI - baseline, 1, 3, 6 months
3. Cognitive function: All tests deleted, replaced with Arizona Cognitive Test Battery (ACTB) (Added 31/05/2011)
4. Adverse events: Side effects associated with CPAP usage, such as dry mouth - baseline and monthly thereafter, + 1 week after commencing treatment
5. Compliance with CPAP: Average hours of use per night from in-built machine timeclocks - baseline, 1, 3, 6 months
6. Carer burden: Modified CBI, GHQ-12, open-ended qualitative comments about the experience of caring - baseline and monthly thereafter

Previous secondary outcome measures:

3. Cognitive function: Leiter-R, BPVSI, Raven Matrices, DSQIID - baseline, 1, 3, 6 months

Completion date

31/12/2014

Eligibility

Key inclusion criteria

For the prevalence study:

1. Age greater than or equal to 16 years, either sex
2. A clinical diagnosis of Down's syndrome

Additionally, for CPAP evaluation:

3. A clinical diagnosis of OSAHS (greater than or equal to 10 obstructive apnoeas hour on multichannel sleep study and symptoms of excessive daytime sleepiness or Epworth Sleepiness Scale [ESS] greater than or equal to 9)
4. Ability to give informed consent and comply with protocol (participant and/or relative/carer, as appropriate)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

28

Key exclusion criteria

1. Previous exposure to CPAP therapy
2. Arterial oxygen saturation less than 90% on room air
3. Participants with forced expiratory volume in one second (FEV1) less than 60%
4. Participants with chronic heart failure or recent myocardial infarction (heart attack)
5. Participants with known moderate or severe dementia
6. Participants with severe behavioural problems that would preclude sleep studies or CPAP treatment
7. Inability to give informed consent AND relative/carer unable or unwilling to give informed consent
8. Inability to comply with the protocol

Date of first enrolment

01/02/2011

Date of final enrolment

31/12/2014

Locations**Countries of recruitment**

United Kingdom

Scotland

Study participating centre**Department of Sleep Medicine**

The Royal Infirmary of Edinburgh

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Sponsor information**Organisation**

University of Edinburgh and NHS Lothian (UK) - Joint Sponsorship

ROR

<https://ror.org/03q82t418>

Funder(s)

Funder type

Government

Funder Name

Chief Scientist Office of the Scottish Executive Health Department (UK) (ref: CZH/4/549)

Funder Name

Fondation Jerome Lejeune (France) (ref: R41361-195RSP)

Funder Name

Added 08/10/2013:

Funder Name

Baily Thomas Charitable Trust (ref: TRUST/RNA/AC/TM/2634-5178)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

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		12/11/2020	27/10/2022	Yes	No
Other publications	Validation of pictorial Epworth sleepiness scale in adults with Down syndrome	01/02/2020	18/12/2020	Yes	No