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Validation of the Alice PDX Diagnostic System in predicting obstructive sleep apnoea (OSA)

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/04/2010	Nervous System Diseases	[ ] Record updated in last year

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
EAME08PDX01

Study information

Scientific Title
Validation of the Alice PDX Diagnostic System in predicting obstructive sleep apnoea (OSA): a single blind randomised crossover study

Acronym
Alice PDX

Study objectives
There will be clinical agreement in the Apnoea Hypopnoea Index (AHI) obtained from simultaneous Alice PDX-in lab and in lab-polysomnographic (PSG) recordings, and the AHI obtained from the PDX-home recording. The differences between the AHI from the PSG and PDX-home will not be greater than two PSGs conducted on two different nights.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Germany: Ethik-Kommission in Witten approved on the 17th March 2009
2. France: Comite de Protection des Personnes Ile de France no. 1 approved on the 27th April 2009

Study design
Single blind randomised crossover study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the sponsor details below to request a patient information sheet

Health condition(s) or problem(s) studied
Obstructive sleep apnoea (OSA)

Interventions
Baseline demographic information will be collected. At baseline symptoms of snoring, sleepiness and associated features of OSA will be captured on the Berlin and Epworth Questionnaires.

Subjects will undergo three sleep evaluations:
1. The Alice PDX will be used at home on one night
2. The Alice PDX will be used at the same time as one of the PSGs in the sleep laboratory on another night
3. A separate PSG will be carried out in the sleep laboratory without the Alice PDX on a third night
The sequence of the sleep evaluations will be determined randomly. All evaluations will take place within a two week period.

As a minimum the following parameters will be obtained:
1. Total recording time
2. Total sleep time
3. Sleep latency
4. Sleep efficiency
5. Sleep stage distribution
6. Arousals
7. Awakenings
8. Apnoea Hypopnoea Index (AHI)
9. Oxygen saturation

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Apnoea Hypopnoea Index (AHI) measured by polysomnography and polygraphy (Alice PDX). Measured over three nights in a random order of either:
1. PDX at home
2. PDX and In-Lab PSG at the same time
3. In-Lab PSG

Secondary outcome measures
1. Apnoea
2. Hypopnoea
3. Supine AHI
4. Total recording time
5. Arousals
6. Desaturation

All will be measured by polysomnography and polygraphy (Alice PDX) as detailed for the primary outcome measures.

Overall study start date
28/09/2009

Completion date
28/09/2010

Eligibility

Key inclusion criteria
1. Male and female patients greater than 21 years of age
2. Suspected obstructive sleep apnoea (OSA) or (or suspected simple snorers)
3. Ability to provide consent
4. Ability and willingness to follow study procedures

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Previous diagnosis of OSA
2. Presence or suspicion of another sleep disorder
3. Acute illness (including cardiac and pulmonary diseases), medically complicated or medically unstable
4. Patients requiring supplemental oxygen or mechanical ventilation
5. Drug abuse (both acute and chronic) according to the Drug Abuse Screening Test (DAST) criteria
6. Alcohol abuse (both acute and chronic) according to the CAGE criteria
7. Intake of excessive central relevant drugs, sedatives, or other drugs which impair sleep, as judged by the investigator
8. Psychiatric or neurological diseases resulting in impairment of sleep
9. Thyroidal dysfunction
10. Chronic pain syndromes
11. Chronic cardiac, pulmonary or other internal diseases resulting in impairment of sleep
12. Unwilling to participate in the study
13. Participation in another clinical study in the past 4 weeks

Date of first enrolment
28/09/2009

Date of final enrolment
28/09/2010

Locations

Countries of recruitment
France

Germany

Study participating centre
HELIOS-Klinik Hagen-Ambrock
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Sponsor information

Organisation
Respironics International, Inc (France) - Philips Home Healthcare Solutions

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Sponsor type
Industry

Website
http://www.respironics.com

ROR
https://ror.org/05jz46060

Funder(s)

Funder type
Industry

Funder Name
Respironics International, Inc (France) - Philips Home Healthcare Solutions

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