

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

Submission date 28/09/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 12/04/2010	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
Hagen
Germany
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Sponsor information

Organisation

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

Sponsor details

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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