ISRCTN13965929 https://doi.org/10.1186/ISRCTN13965929

Breathing rate monitoring with a wearable device in patients with obstructive sleep apnea

Submission date
28/08/2021

Recruitment status
No longer recruiting

Registration date
06/09/2021

Overall study status
Completed

Last Edited
06/09/2021

Condition category
Nervous System Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Sleep apnea is when your breathing stops and starts while you sleep. The most common type is called obstructive sleep apnea (OSA).
This study is aimed at assessing the accuracy of a new non-invasive, continuous, wrist-worn and wireless monitoring PPG device (Corsano CardioWatch 287) in measuring respiration rate and pulse rate at rest.

Who can participate?
Adults suspected for obstructive sleep apnea and healthy volunteers.

What does the study involve?
All participants receive respiration rate and heart rate monitoring simultaneously by a wrist-worn wearable and by respiratory polygraphy, which includes wearing bands around the chest and abdomen, and a pulse-oximeter. The measurements last one full night.

What are the possible benefits and risks of participating?
There are no direct benefits for the participants involved, since the measurements by the investigational device will not be consulted for diagnosis. There are no direct risks for the participants involved.

Where is the study run from?
Department of Sleep Medicine, Haaglanden Clinics, Nieuwe Parklaan 11, The Hague, The Netherlands

When is the study starting and how long is it expected to run for?
September 2020 to March 2021

Who is funding the study?
Corsano Health B.V. (unrestricted grant)

Who is the main contact?
Jacky Gehring, j.gehring@haaglandenclinics.nl

Contact information

Type(s)
Scientific

Contact name
Mrs Jacky Gehring

ORCID ID
http://orcid.org/0000-0001-9595-447X

Contact details
Nieuwe Parklaan 11
Den Haag
Netherlands
2597 LA
+31 649933066
j.gehring@haaglandenclinics.nl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
W20_453 # 20.501

Study information

Scientific Title
Continuous respiration rate monitoring using photoplethysmography technology in patients with obstructive sleep apnea

Study objectives
The mean absolute error and root mean square deviation of respiration rate measured by the Corsano CardioWatch 287 compared to respiratory polygraphy are hypothesized to be less than 1 breath per minute.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 22/10/2020, Medisch Ethische Toetsingscommissie AMC (Meibergdreef 9
1105 AZ Amsterdam, The Netherlands; +31 (0) 20-5667389; no email provided), ref: W20_453 # 20.501

Study design
Single-centre observational study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Home

Study type(s)
Screening

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Obstructive sleep apnea

Interventions
Subjects with and without diagnosed Obstructive Sleep Apnea (OSA) will undergo simultaneous, continuous overnight PPG and respiratory polygraphy (RP), which includes respiratory inductance plethysmography and pulse-oximetry, for one night. The PPG sensor’s respiration rate and pulse rate measurement accuracy will be assessed through Bland Altman and correlation analysis.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Corsano CardioWatch 287-1

Primary outcome measure
Respiration rate and heart rate as measured by the Corsano CardioWatch 287 and respiratory polygraphy, continuously for one night

Secondary outcome measures
There are no secondary outcome measures

Overall study start date

01/09/2020

Completion date
11/03/2021

Eligibility

Key inclusion criteria
1. Patients suspected of Obstructive Sleep Apnea scheduled for overnight respiratory polygraphy, and healthy volunteers
2. Aged 18 years or above

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
26

Total final enrolment
26

Key exclusion criteria
1. Wearer of cardiac implanted electronic device (Pacemaker, ICD)
2. CardioWatch 287 cannot be worn due to comprehensible reasons (allergic reactions, wounds, amputations, other)
3. Unable or not willing to sign informed consent
4. Significant mental or cognitive impairment
5. Currently enrolled in another clinical investigation in which the intervention might compromise the safety of the subject's participation in this study

Date of first enrolment
15/12/2020

Date of final enrolment
11/03/2021

Locations

Countries of recruitment
Netherlands

Study participating centre
Haaglanden Clinics
Nieuwe Parklaan 11
Den Haag
Netherlands
2597 LA

Sponsor information

Organisation
Stichting Haaglanden Clinics

Sponsor details
Nieuwe Parklaan 11
Den Haag
Netherlands
2597 LA
+31 (0) 70 221 21 21
info@haaglandenclinics.nl

Sponsor type
Hospital/treatment centre

Website
https://haaglandenclinics.nl/

Funder(s)

Funder type
Industry

Funder Name
Corsano Health B.V.

Results and Publications

Publication and dissemination plan
Planned publication in Journal of Clinical Sleep Medicine.

Intention to publish date

01/11/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Jacky Gehring, srs@jackygehring.nl. The anonymized raw data will be provided for reproduction purposes only, until 10 years after publication.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			06/09/2021	No	Yes
Protocol file			06/09/2021	No	No