

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

Submission date 28/08/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 06/09/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/09/2021	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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Additional identifiers

Protocol serial number

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

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Funder(s)**Funder type**

Industry

Funder Name

Corsano Health B.V.

Results and Publications

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