

Sleep Revolution - evaluation of a novel diagnostic and therapeutic pathway for patients with obstructive sleep apnea

Submission date 31/08/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/02/2024	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/11/2025	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Obstructive sleep apnea (OSA) is when your breathing stops and starts while you sleep, and is associated with various health complications such as a high risk of heart disease, high blood pressure and daytime sleepiness. Despite its negative impact and various associated illnesses, OSA remains poorly diagnosed and ineffectively treated. The EU-funded SLEEP REVOLUTION project is introducing an approach based on machine learning to assess OSA severity and treatment needs. The current study compares the standard care model of sleep apnea diagnosis with a novel approach to study sleep in the patients' homes for 3 nights instead of one single night. In order to analyse the data faster and more accurately, new computer-based analysis will be used to evaluate the large amount of data. It is one aim of the study to identify markers during sleep that are better at predicting patients' symptoms of sleep problems compared to current diagnostic procedures. A novel sleep question will be developed and evaluated for the first time in this study. One important aspect of the current study is that 24 sleep centers in more than 15 European countries are involved in the study. Up to 1000 patients with suspected sleep apnea across Europe are intended to include in this study.

Who can participate?

Patients aged 18 years and over with suspected sleep apnea referred by their physicians to one of the study centers

What does the study involve?

The study compares the traditional way of sleep diagnosis with a comprehensive sleep study in the hospital or a simplified sleep study at home with a novel approach to perform a comprehensive sleep study for three nights at home. In the novel setting, the patient will be more participatory in the sleep diagnostic process, both by performing the test at home and by providing more information on actual sleep complaints and lifestyle factors. The outcome of those different diagnostic processes will be compared.

What are the possible benefits and risks of participating?

Sleep tests do not include any major risk, only skin lesions may occur through the placement of

electrodes on the skin. More comprehensive sleep tests may cause discomfort without medical harm. The benefits include more detailed knowledge about sleep quality and the number of severity of sleep apnea events. Further, the new diagnostic principle has a strong focus on a variety of sleep-related symptoms and consequences, it is more patient-centred.

Where is the study run from?

Sahlgrenska University Hospital (Sweden)

When is the study starting and how long is it expected to run for?

March 2020 to February 2025

Who is funding the study?

European Commission

Who is the main contact?

Ludger Grote, ludger.grote@lungall.gu.se

Contact information

Type(s)

Principal investigator

Contact name

Prof Ludger Grote

ORCID ID

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Additional identifiers

Protocol serial number

SR 001.3

Study information

Scientific Title

A randomized cross over trial exploring the Sleep Revolution diagnostic and therapeutic pathway in patients with obstructive sleep apnea

Acronym

Sleep Revolution WP 8 study

Study objectives

The current study is a major work package within the overall Sleep Revolution (SR) project. The study focuses on the evaluation of the new SR pathway for sleep apnea diagnosis and treatment follow-up. The feasibility of the following new technologies including patient-related symptom assessment methodology, and data analysis approaches, will be evaluated:

1. Self-applied polysomnography
2. Diagnostic assessment over long time periods including 3 consecutive nights of advanced sleep testing, at least one week of testing with actigraphy, physical activity, sleep symptom questionnaire, and sleep diary
3. Artificial intelligence-based analysis of sleep tests for characterization of sleep, respiratory events and cardiovascular function with quality control by healthcare professionals (semi-automated process)
4. Digital platform for data transfer from the patient to the health care professional
5. Validation of new sleep parameters like hypoxic burden, sleep disturbance index and pulse wave derived cardiovascular indices against comorbidities, baseline symptoms, and response to treatment
6. To evaluate the novel European Sleep Questionnaire (ESQ)

Ethics approval required

Ethics approval required

Ethics approval(s)

submitted 13/11/2023, Swedish Ethical Review Authority (Box 2110, Uppsala, 75002, Sweden; +46 (0)10-475 08 00; registrator@etikprovning.se), ref: 2023-03829-01

Study design

Multi-center two-arm randomized cross-over study

Primary study design

Interventional

Study type(s)

Diagnostic, Treatment

Health condition(s) or problem(s) studied

Sleep apnea

Interventions

Study SR-001 is a multi-center, two-arm, cross-over study comparing the diagnostic impact and accuracy of two different diagnostic pathways on the outcome of diagnosis and continuous positive airway pressure (CPAP) treatment in patients with suspected obstructive sleep apnea (OSA). Patients referred to one of 24 sleep centers of the Escuela Superior de Arte y Diseño de Andalucía (ESADA) network participating in the Sleep Revolution project will be studied using both the clinical routine of OSA evaluation (standard care [SC]) and the novel Sleep Revolution-based diagnostic pathway including self-applied polysomnography over 3 nights, digitally based symptom evaluation, and actigraphy-based assessment of sleep-wake rhythm and physical activity (experimental condition).

Randomisation is carried out in blocks of four patients, and a randomisation list will be distributed to each participating centre in the study. The randomisation list was generated by a publicly available service at <https://www.sealedenvelope.com/simple-randomiser/v1/lists> on 17

August 2023 with the seed for the randomization list of 275031337567920. Actual randomization will be performed at each study site by personnel otherwise not involved in the study.

Standard sleep diagnostic procedure (standard care pathway): Single night polygraphy or polysomnography both at baseline. Limited numbers of questionnaire data.

The experimental setting (Sleep Revolution pathway) includes three nights of self-applied polysomnography, app-based assessment of symptoms, sleep diary, cognitive function and physical activity. Actigraphy-based assessment of sleep-wake cycle and objective physical activity. In case of clinically relevant sleep apnea according to the results of the diagnostic assessment, patients will be offered treatment for sleep apnea with CPAP.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Not applicable

Primary outcome(s)

Staff time spent for the sleep apnea diagnostic pathway – comparison between Standard Care (SC) and the Sleep Revolution (SR) model in patients with suspected obstructive sleep apnea (OSA) from patient inclusion to final consultation with the sleep physician (units: minutes)

Key secondary outcome(s)

1. Patient satisfaction and preference with the diagnostic work-up (score of the patient global impression scale and the patient preference question) at visit 1c: end of diagnostic procedure
2. Patient satisfaction with the resolution of the initial help request through diagnosis and treatment (only in patients with CPAP therapy, specific question in the European Sleep Questionnaire) at V3b: end of study follow-up visit
3. Number of OSA diagnoses, Positive Airway Pressure (PAP) treatment prescriptions, and non-PAP prescriptions by either pathway (number of patients in each group) at V1c and V3b
4. Number of patients with PAP failure (no acceptance/low adherence) by either pathway (number of patients in each group) at V3b
5. Prediction of PAP treatment responders in terms of adherence and symptom improvement by novel diagnostic parameters (SR versus SC) (predictor analysis of adherence with PAP treatment in h/night, conventional diagnostic markers versus novel diagnostic markers) at V3b
6. Association between sleep test output variables (polysomnography [PSG] and home sleep apnea test [HSAT]) (respiration, hypoxia, cardiovascular function, sleep) and symptoms /comorbidities obtained in SC and SR at V1c

Completion date

28/02/2025

Eligibility

Key inclusion criteria

Main Inclusion Criteria:

1. Referral to the sleep center due to suspected obstructive sleep apnea as the main question for evaluation
2. Male or female aged 18 years and above
3. Willing and able to provide written informed consent
4. Willing and able to comply with the study design schedule and other requirements (e.g. no long-term travel conflicting with the planned visits throughout the study)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

1037

Key exclusion criteria**Main Exclusion Criteria:**

1. Any ongoing treatment for OSA or central sleep apnea (CSA)
2. Known significant hypercapnic respiratory failure due to chronic obstructive pulmonary disease or other respiratory condition
3. Any other clinically determined contraindication for PAP treatment
4. Patients participating in any type of weight loss treatment program
5. Unstable congestive heart failure or angina pectoris
6. Any other condition – to the judgement of the investigator – which potentially may jeopardize the completion of the study according to protocol
7. History of alcohol or drug abuse during the last year, substance use disorder at screening

Date of first enrolment

20/12/2023

Date of final enrolment

28/02/2025

Locations**Countries of recruitment**

Belgium

Croatia

Cyprus

Czech Republic

Denmark

Finland

France

Germany

Greece

Ireland

Italy

Poland

Portugal

Romania

Sweden

Türkiye

Study participating centre

Center for Sleep and Wake Disorders

Sahlgrenska Academy
Gothenburg University
Medicinaregatan 8B
Gothenburg
Sweden
41346

Study participating centre

Sleep Unit

Department of Pneumonology
Democritus University of Thrace
Alexandroupolis
Greece

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Study participating centre

Multidisciplinary Sleep Disorders Centre

Antwerp University Hospital and University of Antwerp

Antwerp

Belgium

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Study participating centre

Multidisciplinary Sleep Disorders Centre

Antwerp University Hospital and University of Antwerp

Antwerp

Belgium

-

Study participating centre

Pulmonary Medicine

National and Kapodistrian University of Athens

Athens

Greece

-

Study participating centre

Charité – Universitätsmedizin Berlin

Berlin

Germany

-

Study participating centre

Sleep Disorders Unit

Department of Respiratory Medicine

Medical School

University of Crete

Crete

Greece

-

Study participating centre

Department of Respiratory Medicine

St Vincent's University Hospital

Dublin

Ireland

-

Study participating centre

Pulmonary and Sleep Disorders Unit

St. Vincent's University Hospital

Dublin

Ireland

-

Study participating centre

Sleep Disorders Center

Pulmonary Department

Sahlgrenska University Hospital

Göteborg

Sweden

-

Study participating centre

Université Grenoble Alpes

INSERM HP2 (U1042)

Grenoble University Hospital

Grenoble

France

-

Study participating centre

Department of Chest Diseases

Ege University

Izmir

Türkiye

-

Study participating centre

Department of Sleep Medicine

National Institute of Mental Health

Klecaný

Czech Republic

-

Study participating centre
Department of Respiratory Medicine
Hospital de Santa Maria
Lisbon
Portugal

-

Study participating centre
Dries Testelmans
Sleep Disorders Centre
University Hospital Gasthuisberg
Leuven
Belgium

-

Study participating centre
Department of Respiratory Diseases
Louvain University Center for Sleep and Wake Disorders (LUCS)
University Hospitals Leuven
KU Leuven
Leuven
Belgium

-

Study participating centre
ENT department
Mainz University Hospital
Mainz
Germany

-

Study participating centre
Istituto Auxologico Italiano
IRCCS
Department of Cardiovascular, Neural and Metabolic Sciences
St Luke Hospital
Milan
Italy

-

Study participating centre
Department of Medicine and Surgery
University of Milano-Bicocca
Milan
Italy

-

Study participating centre
PROMISE Dept.
University of Palermo
Palermo
Italy

-

Study participating centre
Unità Operativa di Medicina del Sonno
Istituto Scientifico di Pavia IRCCS
Pavia
Italy

-

Study participating centre
Pulmonology Department Hospital São João
Medicine Faculty of Porto University
Porto
Portugal

-

Study participating centre
Sleep Disorders Centre
Pulmonary Clinic
Solingen
Germany

-

Study participating centre
Sleep Medicine Center
Department of Neuroscience
University of Split School of Medicine

Split
Croatia

-

Study participating centre

Respiratory Failure Unit

G. Papanikolaou Hospital

Thessalonika

Greece

-

Study participating centre

Pulmonary Department

Victor Babes University of Medicine and Pharmacy

Victor Babes Hospital

Timisoara

Romania

-

Study participating centre

Division of Medicine

Department of Pulmonary Diseases

Turku University Hospital and Sleep Research Centre

Department of Pulmonary Diseases and Clinical Allergology

University of Turku

Turku

Finland

-

Study participating centre

2nd Department of Respiratory Medicine

Institute of Tuberculosis and Lung Diseases

Warsaw

Poland

-

Sponsor information

Organisation

Directorate-General for Research and Innovation

ROR

<https://ror.org/01ef4as46>

Funder(s)

Funder type

Government

Funder Name

European Commission

Alternative Name(s)

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during the current study may be available upon reasonable request from Danielle Knieriem (daniellek@ru.is). Further details will be published at a later stage.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.3	29/05/2023	26/06/2025	No	No
Statistical Analysis Plan	version 2.0	26/06/2025	26/06/2025	No	No
Statistical Analysis Plan	version 2.1	04/07/2025	04/07/2025	No	No
Statistical Analysis Plan	Amendment	03/11/2025	03/11/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes