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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

Registration date
23/02/2024

Overall study status
Completed

Last Edited
04/07/2025

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

Study website
https://sleeprevolution.eu/en/home/

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

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

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Diagnostic, Treatment

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

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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not applicable

Primary outcome measure
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)

Secondary outcome measures
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

Overall study start date
01/03/2020

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

1000, according to power analysis (non-inferiority design) based on time estimates in SC and SR care models, 1000 patients need to be randomized (500 patients in each of the 2 diagnostic pathways) corresponding to 42 patients per ESADA study centre. An interim analysis will be performed after 500 patients to determine the final number of patients to be included.

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
-

Study participating centre
Multidisciplinary Sleep Disorders Centre
Antwerp University Hospital and University of Antwerp
Antwerp
Belgium
-

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
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Study participating centre
Department of Respiratory Medicine
St Vincent´s University Hospital
Dublin
Ireland
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Study participating centre
Pulmonary and Sleep Disorders Unit
St. Vincent’s University Hospital
Dublin
Ireland
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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
Klecany
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
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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
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Study participating centre
PROMISE Dept.
University of Palermo
Palermo
Italy
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Study participating centre
Unità Operativa di Medicina del Sonno
Istituto Scientifico di Pavia IRCCS
Pavia
Italy
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Study participating centre
Pulmonology Department Hospital São João
Medicine Faculty of Porto University
Porto
Portugal
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Study participating centre
Sleep Disorders Centre
Pulmonary Clinic
Solingen
Germany
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Study participating centre
Sleep Medicine Center
Department of Neuroscience
University of Split School of Medicine
Split
Croatia
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Study participating centre
Respiratory Failure Unit
G. Papanikolaou Hospital
Thessalonika
Greece
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Study participating centre
Pulmonary Department
Victor Babes University of Medicine and Pharmacy
Victor Babes Hospital
Timisoara

Romania
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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
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Study participating centre
2nd Department of Respiratory Medicine
Institute of Tuberculosis and Lung Diseases
Warsaw
Poland
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Sponsor information

Organisation
Directorate-General for Research and Innovation

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Sponsor type
Government

Website
http://ec.europa.eu/research/index.cfm?pg=dg

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, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
It is planned to publish the results of this major study on approximately 1000 patients in several papers submitted to high-ranking medical peer-reviewed journals after the finalization of the study in 2025.

Intention to publish date
31/12/2025

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