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Co-morbid insomnia and OSA (COMISA) treatment trial using Oral Appliance Therapy

Submission date
01/11/2024

Recruitment status
Recruiting

Registration date
07/11/2024

Overall study status
Ongoing

Last Edited
17/02/2025

Condition category
Nervous System Diseases

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

Plain English summary of protocol
Background and study aims
COMISA, which refers to co-existing insomnia and obstructive sleep apnea (OSA), is a highly debilitating disorder with a general population prevalence of 6%. Up to 50% of people with OSA have insomnia and 40% of people with insomnia have OSA. Positive airway pressure (PAP) use has been associated with a reduction in insomnia in some patients and is currently the standard of care for patients suffering from COMISA. Conversely, cognitive behavioural therapy for insomnia (CBTi) has been associated with a small decrease in OSA severity, probably because it consolidates sleep periods and reduces sleep-wake transitions to improve airway stability. Patients with COMISA experience significantly lower rates of PAP acceptance and use compared to those with OSA alone. Considering the high prevalence and mortality risk associated with unmanaged COMISA, alternative treatment approaches are required. Initial evidence suggests that oral appliance therapy (OAT) may be a favourable therapy in patients with COMISA, which will be more acceptable to patients, and reduce symptoms of both insomnia and OSA. To date, no previous study has investigated combinations of OAT and CBTi in patients with COMISA. Therefore, more research is required to investigate the real-world clinical utility of OAT paired with CBTi for the management of COMISA. This will be the focus of the POCC Pilot Study. The POCC Trial (pilot study) describes a clinical management protocol aimed at improving the care of patients with OSA, insomnia, and particularly those with overlapping conditions like COMISA. This observational study aims to investigate a novel management model for COMISA, combining CBTi, PAP therapy, and OAT.

Who can participate?
Consecutive patients aged between 18 and 80 years old enrolled in Ontario sleep clinics who are diagnosed with COMISA.

What does the study involve?
The protocol involves offering OAT after the prescription of PAP therapy for patients who refuse /cannot tolerate PAP. This sequential approach is not universally implemented for the care of OSA or COMISA, however, it is aligned with AASM and AADSM guidance.

Specifically, participants will be offered aPAP to manage their OSA. If adherent, they will be offered a cognitive behavioral therapy for insomnia (CBT-I) program for their insomnia. Once

complete, they will take a final in-lab sleep study. If intolerant to, or through refusal of aPAP, they will be offered OAT. If adherent, they will be offered a CBTi program for their insomnia. Once complete, they will take a final in-lab sleep study.

Questionnaires will be completed 3 and 12 months after the final sleep study to establish the continued benefits of therapy. Once all questionnaires have been completed, the study obligations end, and study participants will continue to be monitored by their doctors as per usual and customary protocols.

What are the possible benefits and risks of participating?
Potential benefits include formalized guidance-based care and systematic scheduling, compilation of patient-centred and laboratory outcomes and cost savings for participants who complete all protocol steps.

Where is the study run from?
Sleep Disorders Dentistry Research and Learning Centre (Canada)

When is the study starting and how long is it expected to run for?
November 2024 to June 2026

Who is funding the study?
1. Panthera Dental, Canada (partial)
2. Investigator initiated and funded

Who is the main contact?
Dr Sherif Elsaraj, sherifelsaraj.cissso@ssss.gouv.qc.ca, Sherif.Elsaraj@McGill.Ca

Study website
https://www.youtube.com/watch?v=23bxnzPpFws

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
240-402

Study information

Scientific Title
PAP-OAT-CBTi -COMISA Trial (POCC Trial)

Acronym
POCC Trial

Study objectives
High adherence to oral appliance therapy (OAT) positions it as the preferred treatment alternative for patients suffering from co-morbid insomnia and obstructive sleep apnea (COMISA) compared to continuous positive airway pressure (PAP) therapy, which shows significantly lower adherence rates among this population.

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted, Research Center Department of Education, University Relations and Research Integrated Center for Health and Social Services of Outaouais (Centre de Recherche Direction de L'enseignement, des Relations Universitaires et de la Recherche Centre Intégré de Santé et de Services Sociaux de L'outaouais) (909, Boulevard La Vérendrye O, Gatineau (Québec), J8P 7H2, Canada; +1 (819) 966-6000; manon.dupuis@ssss.gouv.qc.ca), ref: Reference number not provided

Study design
Observational case-crossover study

Primary study design
Observational

Secondary study design
Case crossover study

Study setting(s)
Dental clinic, Medical and other records

Study type(s)
Screening, Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Co-existing insomnia and obstructive sleep apnea (OSA) (COMISA)

Interventions
This is a patient management protocol with a formal care pathway. The goal is to offer the protocol to consecutive patients in Ontario sleep clinics. Oral appliance therapy (OAT) utilizes a custom-made, adjustable FDA-cleared appliance specifically made to assist breathing by keeping the tongue and jaw in a forward position during sleeping hours. The formalized sequence of offering OAT after a prescription of continuous positive airway pressure (PAP) therapy is not universally implemented for the care of obstructive sleep apnea (OSA) or more specifically co-morbid insomnia and obstructive sleep apnea (COMISA). Therefore, this pilot study will document outcomes associated with offering OAT for patients suffering from COMISA, if they prove intolerant to or refuse PAP. This trial is particularly important as the absence of data regarding outcomes with this protocol currently results in many of these patients remaining unmanaged.

Participants will be offered aPAP to manage their OSA. If adherent, they will be offered a cognitive behavioral therapy for insomnia (CBT-I) program for their insomnia. Once complete, they will take a final in-lab sleep study. If intolerant to, or through refusal of aPAP, they will be offered OAT. If adherent, they will be offered a CBTi program for their insomnia. Once complete, they will take a final in-lab sleep study.

Questionnaires will be completed 3 and 12 months after the final sleep study to establish the continued benefits of therapy. Once all questionnaires have been completed, the study obligations end, and study participants will continue to be monitored by their doctors as per usual and customary protocols.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Panthera D-SAD

Primary outcome measure
The effectiveness of oral appliance therapy (OAT) in co-morbid insomnia and sleep apnea (COMISA) patients who are resistant or intolerant to PAP therapy is assessed using the following questionnaires at baseline, 3 and 12 months:
1. Daytime sleepiness measured using the Modified Epworth Sleepiness Scale (ESS)
2. The impact of sleepiness on daily activities measured using the Functional Outcomes of Sleep Questionnaire (FOSQ-10)
3. Patient-reported sleep quality and well-being measured using the Sleep Wellbeing Index for Treatment (SWIFT)
4. sleep duration, quality, and disturbances measured using the RAND Sleep Questionnaire
5. The severity of insomnia symptoms measured using the Insomnia Severity Index (ISI)

Secondary outcome measures
1. Impact of insomnia symptoms on adherence to PAP or OAT: Outcome: Influence of insomnia severity measured using the ISI on treatment adherence at 3 and 12 months
2. Alternative management for PAP non-responders: Outcome: Proportion of patients with PAP intolerance effectively managed with OAT, assessed using improvements in questionnaire scores
3. Effect of OAT on insomnia symptoms: Outcome: Change in ISI scores at 3 and 12 months
4. Dose-response relationship between OAT use and insomnia improvement: Outcome: Correlation between OAT usage frequency (hours per night) and ISI score reduction
5. Integration of OAT into current models of care: Outcome: Feasibility based on adherence rates and patient satisfaction (SWIFT scores)
6. Prevalence of COMISA in in-lab sleep study patients: Outcome: Proportion with COMISA identified in baseline assessments using the modified ESS and ISI

Overall study start date
01/11/2024

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Adults 18-80 years of age
2. Non-pregnancy
3. Polysomnography (PSG) diagnosis available
4. Insomnia diagnosis
5. For OAT: More than 10 healthy teeth per arch with a healthy temporomandibular joint (TMJ)
6. For PAP: Must be a candidate for APAP set at 5-15 cmH2O pressure
7. Competent and able to comprehend English and sign consent form

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
Not meeting the participant inclusion criteria

Added 17/02/2025:
1. Less than 18 years of age
2. Pregnancy
3. No polysomnography (PSG) diagnosis available
4. No insomnia diagnosis
5. Presents with TMJ-related pain
6. Not competent and able to comprehend English and unable to sign the consent form

Date of first enrolment
01/04/2025

Date of final enrolment
10/12/2025

Locations

Countries of recruitment
Canada

Study participating centre
Sleep Disorders Dentistry Research and Learning Centre
5045 Orbitor Drive, Unit 10-300
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Sponsor information

Organisation
Panthera Dental

Sponsor details
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Sponsor type
Industry

Website
https://pantherasleep.com/#dna

Funder(s)

Funder type
Industry

Funder Name
Panthera Dental

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Knowledge translation and dissemination are essential for transforming clinical trial results into practical applications that enhance patient care and improve healthcare systems. Effective knowledge translation involves synthesizing research findings and communicating them clearly to various stakeholders, including healthcare providers, policymakers, and the public. Strategies for dissemination may include workshops, publications, and digital platforms, which help bridge the gap between research and practice. Additionally, engaging stakeholders through interactive forums and social media can facilitate broader outreach and foster collaboration. Tailoring messages to the specific needs of diverse audiences ensures that evidence-based practices are more readily adopted. By actively promoting research findings and creating an environment of continuous learning, we can significantly improve the integration of new knowledge into everyday clinical settings, ultimately leading to better patient outcomes and a more informed healthcare community.

Intention to publish date

10/01/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Sherif Elsaraj, sherifelsaraj.cissso@ssss.gouv.qc.ca. All data collected will be entered into an Excel document that is confidential. The study participants will be assigned a number in a computer hard drive which will be destroyed by https://www.shredit.com/en-ca/secure-shredding-services/hard-drive-destruction. Their names corresponding to the numbers assigned will be stored in a locked desk with a key in the private clinic office of Sleep Disorders Dentistry Research and Learning Centre.

Oral Appliance Bite Registration Data:
• Vertical and Level of Protrusion
o Baseline Mandibular range (Full Retrusive to Full Protrusive)
o Baseline Most Advanced Protrusive Position of Comfort
o Final Tested Position (Vertical and Level of Protrusion)

Modified ESS Questionnaire:
https://nasemso.org/wp-content/uploads/neuro-epworthsleepscale.pdf

FOSQ10 Questionnaire:
https://www.serenitymedicalservices.com/wp-content/uploads/2020/01/CEREVES_FOSQ_10_ENG.pdf

SWIFT Questionnaire:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3501668/

RAND Questionnaire: https://www.rand.org/content/dam/rand/www/external/health/surveys_tools/mos/mos_sleep_survey.pdf

ISI Questionnaire:
https://www.sleepprimarycareresources.org.au/questionnaires/isi

• At Baseline and all endpoints: All the above is captured with PSG and questionnaire.
• At 3 months patient will take 7 nights of Home Sleep Testing with the Belun Ring.
• At 3 and 12 months post reaching treatment endpoint: Questionnaires and questions provide ongoing assessment of maintenance of outcomes, and ongoing adherence.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.01		08/11/2024	No	Yes
Participant information sheet	version 1.01		08/11/2024	No	Yes
Participant information sheet			08/11/2024	No	Yes
Participant information sheet			08/11/2024	No	Yes
Protocol file	version 3.2		08/11/2024	No	No