ISRCTN13124681 https://doi.org/10.1186/ISRCTN13124681

PillowsPlus nasal cannula for sleep

Submission date
24/09/2025

Recruitment status
No longer recruiting

Registration date
10/10/2025

Overall study status
Completed

Last Edited
02/10/2025

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
This study is testing a new nasal oxygen interface, called the PillowsPlus Nasal Cannula (PPNC). The goal is to see if it improves oxygen delivery during sleep for patients who use long-term oxygen therapy. Standard nasal cannulas can fail to deliver enough oxygen when people breathe through their mouths or during sleep. The new device is designed to fix this problem by making portable oxygen concentrators more reliable.

Who can participate?
Adults (18 years and older) prescribed up to 6 liters per minute of oxygen can join. People with moderate or severe sleep apnea, those who need nighttime CPAP/BiPAP, or those fully dependent on mechanical ventilation cannot take part. Patients with significant facial injuries that prevent use of nasal cannulas are also excluded.

What does the study involve?
Participation lasts about 4 days. Each participant completes three overnight sleep studies at home wearing a pulse oximeter and using different combinations of oxygen equipment:
Night 1: Standard cannula with a stationary oxygen concentrator.
Nights 2 and 3: Either the new PPNC or a standard cannula with a portable concentrator (order randomized).
Oxygen levels and heart rate are recorded, and participants fill out comfort questionnaires.

What are the possible benefits and risks of participating?
Potential benefits include helping to improve portable oxygen therapy devices for future patients. Risks are minimal but may include discomfort from the cannula or lower oxygen levels. A physician will review safety data, and unsafe results will lead to stopping further testing for that participant.

Where is the study run from?
Northern Alberta Institute of Technology (NAIT) (Canada)

When is the study starting and how long is it expected to run for?
August 2024 to August 2025

Who is funding the study?
Pulmvita Inc. with support from Alberta Innovates (AICE–Validate Grant and Health Innovation Platform Partnership Grant) (Canada)

Who is the main contact?
Dr Daniel Vis, daniel.vis@ucalgary.ca

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Daniel Vis

ORCID ID
https://orcid.org/0009-0002-9343-626X

Contact details
4448 Front St SE
Calgary
Canada
T3M 1M4
+1 (0)403 956 2800
daniel.vis@ucalgary.ca

Additional identifiers

Protocol serial number
Health Canada Investigational Testing Authorization #381594

Study information

Scientific Title
Determining the effects of a PillowsPlus Nasal Cannula on oxygenation during ambulation and sleep

Study objectives
The study aims to determine the effects of the PillowsPlus Nasal Cannula (PPNC) on oxygenation during sleep.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 26/08/2024, University of Alberta Research Ethics Office (11312 – 89 Avenue NW, Edmonton, T6G 2N2, Canada; +1 (0)780 492 9724; reoffice@ualberta.ca), ref: UofA REB ID: Pro00148005

2. Approved 26/08/2024, Northern Alberta Institute of Technology Research Ethics Board (11762 - 106 Street, Edmonton, T5G 2R1, Canada; +1 (0)780 471 6248; reb@nait.ca), ref: NAIT REB ID: 2024-08

Primary study design
Interventional

Study design
Multicenter interventional single-blinded randomized cross over trial

Study type(s)
Safety

Health condition(s) or problem(s) studied
Nocturnal oxygenation in patients on long-term oxygen therapy

Interventions
We performed a three-night, two-sequence cross over study, adults on long-term oxygen therapy slept one night with a standard nasal cannula on a stationary continuous-flow concentrator (baseline), one night with PillowsPlus nasal cannula (PPNC) on continuous flow, and one night with PPNC on a pulsed-flow concentrator. The method of randomization was randomization software set to produce an even distribution across conditions.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
PillowsPlus nasal cannula

Primary outcome(s)
Nocturnal average SpO2 by pulse oximetry, measured at baseline with a standard cannula + stationary concentrator compared to a PillowsPlus nasal cannula + a portable concentrator and a PillowsPlus nasal cannula + stationary concentrator on sequential nights. Designed and powered for non-inferiority.

Key secondary outcome(s)
1. Nocturnal average heart rate by pulse oximetry, measured at baseline with a standard cannula +stationary concentrator compared to a PillowsPlus nasal cannula +stationary concentrator and a PillowsPlus nasal cannula + stationary concentrator on sequential nights.
2. Frequency of oxygen desaturation events of 3% or greater by pulse oximetry, measured by blinded, manual scoring of oximetry data by a respirologist. Baseline recorded with standard cannula +stationary concentrator, compared to a PillowsPlus nasal cannula +stationary concentrator and a PillowsPlus nasal cannula + stationary concentrator on sequential nights.
3. Patient comfort data as measured with patient surveys at baseline with standard cannula +stationary concentrator, compared to a PillowsPlus nasal cannula +stationary concentrator and a PillowsPlus nasal cannula + stationary concentrator on sequential nights.

Completion date

22/08/2025

Eligibility

Key inclusion criteria
Patients aged over 18 years on chronic domiciliary oxygen therapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
27

Key exclusion criteria
1. Requiring >6 L of O2 per minute at baseline
2. Previously established need for any nocturnal positive airway pressure therapy for conditions such as CPAP for obstructive sleep apnea (OSA), ASV for central sleep apnea, or BiPAP for obesity hypoventilation syndrome
3. Patients fully dependent on mechanical ventilation and/or those with facial injuries that preclude the use of a standard cannula or the PPNC will be excluded
4. Patients with an Apnea-Hypopnea Index (AHI) >15 will be excluded from further testing

Date of first enrolment
05/06/2025

Date of final enrolment
22/08/2025

Locations

Countries of recruitment
Canada

Study participating centre
Northern Alberta Institute of Technology
11762 - 106 Street

Edmonton
Canada
T5G 2R1

Study participating centre
University of Alberta
11312 – 89 Avenue NW
Edmonton
Canada
T6G 2N2

Sponsor information

Organisation
Alberta Innovates

ROR
https://ror.org/00ynafe15

Funder(s)

Funder type
Industry

Funder Name
Pulmvita Inc.

Funder Name
Alberta Innovates

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Efrem Violato (efrem@nait.ca) or Daniel Vis (daniel.vis@ucalgary.ca).
The study will collect oxygen saturation and heart rate data from pulse oximetry, comfort questionnaire responses, and basic demographics. All data are coded by study ID, with identifiers stored separately and securely by the principal investigator.

Data will be stored securely for at least 5 years and then destroyed. Only de-identified, coded datasets are shared between the investigators at NAIT and Pulmvita Inc. Analyses will compare oxygen delivery and patient comfort, with results published in aggregate only.
Data sharing is limited to anonymised files exchanged between research partners; there is no open-access repository. Written informed consent is obtained, and participants may withdraw their data before publication.
Ethical restrictions prevent identifiable data from leaving the study team. Any withdrawals, adverse events, or protocol deviations will be reported in the final outputs.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Comfort Questionnaire		02/10/2025	No	No
Other files	Consent Form		02/10/2025	No	No