ISRCTN30656608 https://doi.org/10.1186/ISRCTN30656608

Tissue oxygen saturation measurement during arterial desaturation study

Submission date 21/08/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 09/09/2019	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 04/06/2020	**Condition category** Other	[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 12/09/2019:
Background and study aims
Chronic changes in arterial oxygen concentration are used as a measure of severity of disease state for a variety of conditions such as sleep apnea, chronic obstructive pulmonary disease, pulmonary arterial hypertension and heart failure. The aim of this study is to get information about how much oxygen can be detected in the tissues of the chest and the fingers of patients with two or more of these conditions. These conditions lower the amount of oxygen in the body. Doctors use measurements of how much oxygen is in the blood to understand how severe someone's condition is. The more doctors know about changes to a person's blood oxygen levels, the earlier they can treat the condition and this can help to keep more people out of the hospital.

Who can participate?
Patients over the age of 18 with one or more of the following conditions: sleep apnea, chronic obstructive pulmonary disease, pulmonary arterial hypertension and heart failure.

What does the study involve?
In order to collect the necessary data for this study, tissue oxygen sensors are placed on the patient's chest and depending on the condition they possess, the patient either undergoes a monitored sleep study or a series of 6-minute walk tests. The data collection visit takes place at a hospital and lasts about 9 hours for sleep study patients and about 45 minutes for 6-minute walk test patients.

What are the possible benefits and risks of participating?
In agreeing to be in this study, there will not be any direct medical benefits. The information from this study may benefit other patients who need monitoring devices for conditions like these in the future. All the risks of using the study devices and having the sleep study or doing a 6-minute walk test are the same whether patients are in the study or not. These risks include, but are not limited to: skin irritation or rash from the adhesives used to attach the sensors to the chest, skin irritation or rash from the adhesive or Velcro that may be used to keep the sensor wires in place for participants doing a sleep study, and for participants doing a sleep study, the wires from the monitor could pose a risk for strangulation.

Where is the study run from?
1. University of Minnesota (USA)
2. Minneapolis Heart Institute (USA)

When is the study starting and how long is it expected to run for?
May 2019 to February 2020 (updated 09/03/2020, previously: March 2020)

Who is funding the study?
Medtronic (USA)

Who is the main contact?
1. Troy Penz
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2. Joy Aso
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Previous plain English summary:
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Who is the main contact?
1. Troy Penz
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2. Joy Aso
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
MDT19020

Study information

Scientific Title
Tissue oxygen saturation measurement during arterial desaturation study

Acronym
TO-SMART

Study objectives
The purpose of this clinical feasibility, observational study is to collect tissue oxygen saturation (StO2) data in the pectoral region while simultaneously collecting peripheral capillary oxygen saturation (SpO2) data in patients with the following morbidities: Sleep Apnea (SA), Chronic Obstructive Pulmonary Disease (COPD), Pulmonary Arterial Hypertension (PAH) and Heart Failure (HF).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 26/11/2019, University of Minnesota Institutional Review Board (McNamara Alumni Center- Suite 350-2, 200 Oak St. SE, Minneapolis, MN 55455, USA)
2. Approved 14/10/2019, Advarra Institutional Review Board (Advarra, 6940 Columbia Gateway Dr Ste 110, Columbia, MD 21046-2788 USA), ref: MOD00520835

Study design
Prospective multi-center non-randomized acute feasibility clinical study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Sleep apnea (SA), chronic obstructive pulmonary disease (COPD), pulmonary arterial hypertension (PAH) and heart failure (HF)

Interventions
The researchers are targeting four patient populations: SA, COPD, PAH and HF. The COPD/PAH /HF cohort will consist of subjects aged ≥ 18 years who are scheduled to undergo a standard of care (SOC) six-minute walk test (6MWT) and are expected to experience a minimum of 5% arterial oxygen desaturation. The Sleep Apnea cohort will consist of subjects aged ≥ 18 years who are scheduled to undergo a SOC sleep study at a sleep lab and are expected to experience a minimum of 5% arterial oxygen desaturation.

At the enrolment and baseline visit, patients sign the informed consent form (ICF) and their physician collects data pertaining to demographic and health history. This will be when the

attending physician assesses if the patient is a good fit for the study. During the data collection visit, tissue oxygen saturation (StO2) and peripheral capillary oxygen saturation (SpO2) will be observed and measured in the patients using sensors. Sleep apnea patients will undergo a sleep study as a means for data collection whereas the COPD/PAH/HF will undergo a series of standard of care 6 Minute Walk Tests. The sleep study and necessary data collection will last approximately 9 hours, whereas the 6 Minute Walk Tests with necessary data collection will run for approximately 45 minutes. At the end of the data collection visit, the subject is able to exit the study. No further follow-up will be required.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Tissue oxygen saturation (StO2) in the pectoral region during tissue oxygen desaturation, measured using external StO2 sensors at a single timepoint

Key secondary outcome(s))
Standard peripheral capillary oxygen saturation (SpO2), measured using an external SpO2 sensor at a single timepoint

Completion date
17/02/2020

Eligibility

Key inclusion criteria
1. Subject must be ≥ 18 years old
2. Subject (or subject's legally authorized representative) is willing and able to provide written informed consent
3. Sleep Apnea cohort: subjects undergoing a scheduled SOC sleep study who are expected to experience a minimum of 5% arterial oxygen desaturation
4. COPD/PAH/HF cohort: subjects undergoing a scheduled SOC 6MWT who are expected to experience a minimum of 5% arterial oxygen desaturation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Total final enrolment
33

Key exclusion criteria
1. Subject has other medical conditions that would limit study participation (per physician discretion)
2. Subject has known allergies to medical adhesives and cannot tolerate placement of NoninTM SenSmartTM EQUANOXTM Advance sensor on chest
3. Subject has a disorder causing poor blood circulation to the fingers or a connective tissue disorder that would interfere with an accurate measurement of SpO2 in the fingers (per physician discretion)
4. Subject is unable or unwilling to participate in study procedures
5. Subject is enrolled in a concurrent study that may confound the results of this study. Co-enrollment is any concurrent clinical study (including registries) requires approval of the study manager or designee
6. Subject with exclusion criteria required by local law

Date of first enrolment
01/10/2019

Date of final enrolment
17/02/2020

Locations

Countries of recruitment
United States of America

Study participating centre
University of Minnesota
717 Delaware Street SE
Minneapolis
United States of America
55414

Study participating centre
Minneapolis Heart Institute
13205 Isle Drive Suite 100
Baxter
United States of America
56425

Sponsor information

Organisation
Medtronic Inc

ROR
https://ror.org/00grd1h17

Funder(s)

Funder type
Industry

Funder Name
Medtronic

Alternative Name(s)
Medtronic Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
No patient data will be made openly available. It will be stored entirely in a Medtronic controlled database for internal use.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		03/06/2020	03/06/2020	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes