

Tissue oxygen saturation measurement during arterial desaturation study

Submission date 21/08/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/09/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/06/2020	Condition category Other	<input type="checkbox"/> 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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2. Joy Aso
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Contact information

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Public

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joy.a.aso@medtronic.com

Additional identifiers

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 Nonin™ SenSmart™ EQUANOX™ 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 in 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