

# Tissue oxygen saturation measurement during arterial desaturation study

<b>Submission date</b> 21/08/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/09/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/06/2020	<b>Condition category</b> 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  
troy.d.penz@medtronic.com
2. Joy Aso  
joy.a.aso@medtronic.com

Previous plain English summary:

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 two 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 January 2020

Who is funding the study?  
Medtronic (USA)

Who is the main contact?  
1. Troy Penz  
troy.d.penz@medtronic.com  
2. Joy Aso  
joy.a.aso@medtronic.com

## Contact information

**Type(s)**  
Public

**Contact name**  
Mr Troy Penz

**Contact details**  
8200 Coral Sea Street NE  
Mounds View  
United States of America  
55112  
+1 (0)763 337 2477  
troy.d.penz@medtronic.com

**Type(s)**  
Public

**Contact name**  
Miss Joy Aso

**Contact details**  
8200 Coral Sea Street NE  
Mounds View  
United States of America  
55112  
+1 (0)401 545 4454  
joy.a.aso@medtronic.com

## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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 (StO<sub>2</sub>) data in the pectoral region while simultaneously collecting peripheral capillary oxygen saturation (SpO<sub>2</sub>) 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

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Diagnostic

**Participant information sheet**

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

**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  $\geq 18$  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  $\geq 18$  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 (StO<sub>2</sub>) and peripheral capillary oxygen saturation (SpO<sub>2</sub>) 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 measure**

Tissue oxygen saturation (StO<sub>2</sub>) in the pectoral region during tissue oxygen desaturation, measured using external StO<sub>2</sub> sensors at a single timepoint

## **Secondary outcome measures**

Standard peripheral capillary oxygen saturation (SpO<sub>2</sub>), measured using an external SpO<sub>2</sub> sensor at a single timepoint

## **Overall study start date**

01/05/2019

## **Completion date**

17/02/2020

# **Eligibility**

## **Key inclusion criteria**

1. Subject must be  $\geq 18$  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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

30

**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<sup>TM</sup> SenSmart<sup>TM</sup> EQUANOX<sup>TM</sup> 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 SpO<sub>2</sub> 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

**Sponsor details**  
8200 Coral Sea Street NE  
Mounds View  
United States of America  
55112  
+1 (0)763 337 2477  
troy.d.penz@medtronic.com

**Sponsor type**  
Industry

**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

**Publication and dissemination plan**

Currently there are no plans for publication of this study outside of ISRCTN.com. No additional documents for this study will be made available.

**Intention to publish date****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?
<a href="#">Basic results</a>		03/06/2020	03/06/2020	No	No