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Tactile stimulus for the prevention of low blood oxygen immediately after surgery

Submission date	Recruitment status	[X] Prospectively registered
15/09/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/09/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/03/2019	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In order to function properly, the human body requires a certain level of oxygen circulating in the blood. The concentration of oxygen in the blood (oxygen saturation) fluctuates throughout the day, but a healthy level is considered to be above 95%. The oxygen saturation can be affected by a number of factors, including obstructive sleep apnea (OSA). OSA is a condition where the throat muscles relax during sleep, blocking the flow of air. This causes a person to stop breathing temporarily (apnea), leading to low oxygen saturation (hypoxemia), which can is potentially fatal. When a person suffering from OSA is sedated, the risk that they will stop breathing is much higher, which can lead to permanent damage or death. It has been suggested that “disturbing” the patient when their oxygen saturation becomes low could help to re-start breathing. An oxistimulator is a device which monitors the oxygen saturation of a patient and provides a small electrical current when the oxygen saturation drops, reducing the length of apnea. The aim of this study is to investigate whether using this device can help to reduce the extent and duration of hypoxemia in post-surgery patients at risk of OSA.

Who can participate?
Adult surgery patients at high risk of obstructive sleep apnea with normal blood oxygen saturation.

What does the study involve?
Participants are randomly allocated into two groups. Those in the first group wear a “sham” device which does not deliver any stimulation to the patient. Those in the second group (intervention group) wear the oxistimulator device on their arm for one hour, immediately after their surgery. Every time oxygen saturation drops below the normal range, the device will stimulate the nerves in the arm using a small electrical current. The extent and length of time that the patients are hypoxemic is monitored throughout the hour that they are wearing the devices. Over the following 72 hours, patients in both groups are monitored for any side effects from the experiment (i.e. discomfort in the arm that wore the device).

What are the possible benefits and risks of participating?
There are no direct benefits for participants, however knowledge will be gained by the investigators about how to treat future patients with hypoxemia. The risks of participating are minor, including potential discomfort from the device and stimulation.

Where is the study run from?
Mayo Clinic (USA)

When is the study starting and how long is it expected to run for?
September 2015 to January 2016

Who is funding the study?
Mayo Clinic (USA)

Who is the main contact?
Mr Richard Hinds
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13-003533

Study information

Scientific Title
A randomized control trial of peripheral nerve stimulation as an adjunct to standard monitoring to reduce hypoxemic events during the post-operative recovery period

Study objectives
Patients that use the active oxistimulator device versus the same device will have higher blood oxygen levels after surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Mayo Clinic Institutional Review Board, 10/07/2015, ref: 13-003533

Study design
Phase I/II double-blinded placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Hypoxemia

Interventions
Patients are randomly allocated into two groups. For participants in the control group, a sham device is used which delivers no peripheral nerve stimulation. For those in the intervention group, the oxistimulator is worn on the arm and provides peripheral nerve stimulation when oxygen saturation becomes low. The treatment period lasts for one hour. Patients in both groups are monitored for 72 hours post anesthesia to record any adverse events, such as discomfort in the extremity the device was worn on, as well as any other unanticipated events.

Intervention Type
Device

Phase
Phase I/II

Primary outcome measure
Cumulative area under the curve with SpO2 below 90% over one hour

Secondary outcome measures

1. Lowest recorded Sp02 over one hour
2. Cummulative time below 90% over one hour
3. Number of nursing interventions in each group

Overall study start date
10/07/2015

Completion date
29/02/2016

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Able to provide written informed consent
3. At high risk for undiagnosed obstructive sleep apnea
4. Having gynecological, colorectal, orthopedic surgery, and urologic surgeries
5. Baseline oxygen saturation on room air > 96%

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Peripheral neuropathy involving the upper extremities
2. Procedures requiring direct admission to the ICU or any site other than the PACU from the OR
3. Diagnosed OSA and / or use of CPAP / BiPAP in the PACU
4. Presence of any implantable electric devices, including internal defibrillators, pacemakers, or left ventricular assist device (LVAD)
5. Post-procedure temperature < 35.5 Celsius or evidence of vasoconstriction
6. Presence of metal hardware in either arm or in either shoulder
7. Patients lacking access to the bare skin on an arm after surgery
8. History of atrial fibrillation
9. History of bundle branch block
10. Females from menarche to menopause that do not have a current negative pregnancy test or surgical history preventing pregnancy.

Date of first enrolment

18/09/2015

Date of final enrolment
01/01/2016

Locations

Countries of recruitment
United States of America

Study participating centre
Mayo Clinic
200 First Street SW
Rochester
United States of America
55901

Sponsor information

Organisation
Mayo Clinic

Sponsor details
200 First Street SW
Rochester
United States of America
55901

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03jp40720

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Mayo Clinic

Results and Publications

Publication and dissemination plan
The results of the trial will be published in a peer reviewed journal.

Intention to publish date
30/06/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date