REVEAL for Respiration Detection (REST)

Published: 01-08-2013
Last updated: 22-04-2024

This study is a prospective, non-randomized, single-center study evaluating the correlation between the respiratory rate derived from the Reveal Insertable Cardiac Monitor (ICM) electrocardiogram (ECG) with the respiratory rate obtained from an...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON38837

Source
ToetsingOnline

Brief title
REST

Condition

- Other condition
- Cardiac arrhythmias

Synonym
cardiac monitor, respiration

Health condition

syncope met onbekende oorzaak

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic B.V.
Source(s) of monetary or material Support: Medtronic Bakken Research Center BV

Intervention

Keyword: detection, respiration, reveal

Outcome measures

Primary outcome

During the study all hemodynamic and electrophysiological data is continuously collected via the holter and respiration band downloads. The primary endpoint for this study is the correlation between the respiratory rate obtained from the ICM ECG and the external respiratory band during normal breathing.

The respiration effects the heart rate such that the heart rate increases during inspiration and decreases during expiration, the fluctuations are extracted from the Reveal ECG by measuring the distance between the R peaks (from the QRS complex) and used to create a time series, a band-width filter is applied to the time series, then two statistical techniques are used to calculate the respiration rate - an autoregressive model and an empirical mode decomposition model.

Secondary outcome

Not applicable

Study description

Background summary

Early recognition of changes in respiratory rate may be useful in monitoring a patient*s disease status. Respiration rate has been shown to be an important antecedent of patient deterioration (Hodgetts, Kenward, Vlachonikolis, Payne, & Castle, 2002). Tachypnoea, the elevation of the respiratory rate, has been

suggested as the most important signal for interventions for the prevention of cardiopulmonary arrests (Fieselmann, Hendryx, Helms, & Wakefield, 1993).

While automated techniques exist for measuring respiratory rate, they usually require the use of equipment which might interfere with natural breathing, such as spirometry (measuring the flow of air in and out during breathing) or might be uncomfortable for the patient, such as inductance plethysmography. Additionally these techniques require dedicated devices and do not allow for a continuous monitoring of patients outside a hospital setting.

Measuring the respiratory rate from an ECG obtained from an implantable cardiac monitor could overcome these limitations and has become more feasible with the development of robust signal processing techniques (O'Brien & Heneghan, 2007) (Orphanidou, Fleming, Shah, & Tarassenko, 2013).

The results from this study will help improve our understanding of the feasibility of extracting the respiratory rate from the Reveal ECG signal and provide data that can be used to design future studies. In the future, monitoring respiratory rate could help indicate progression of cardiopulmonary illnesses, including acute respiratory distress syndrome, pulmonary edema, pulmonary embolism, pneumonia, COPD, and severe heart failure and be used to improve the quality of care for patients by providing timely information to help diagnosis and manage the patients.

Study objective

This study is a prospective, non-randomized, single-center study evaluating the correlation between the respiratory rate derived from the Reveal Insertable Cardiac Monitor (ICM) electrocardiogram (ECG) with the respiratory rate obtained from an external respiratory band in patients previously implanted with a Reveal for unexplained syncope or suspected arrhythmia.

Study design

Subjects previously implanted with a Reveal for unexplained syncope or suspected arrhythmia will be invited to participate and attend a single study visit. The study visit is expected to take no more than 3 hours.

During the study visit the respiration band and Holter monitor will be placed on the subject. Subjects will be studied in a quiet room, while in the supine position. Subjects will be asked to perform a series of breathing exercises. The breathing patterns will last up to 3 minutes each and will be separated by a minimal amount of time to prepare for the next maneuver. Subjects will breathe in the following patterns:

•Normal Breathing

Measurements will be taken to record normal breathing at the subject*s spontaneous rate and tidal volume for 3 minutes.

•Periodic Breathing
A periodic breathing pattern will be recorded with consists of 20 seconds of voluntary apnea followed by 30 seconds of spontaneous respiration. The pattern will be repeated for up to 3 minutes. Subjects will be prompted when to breathe and when to hold their breath.

•Controlled Breathing
Up to 3 minutes of metronome-set breathing at 12 breaths/min will be collected.

•Posture Changes
3 minutes of normal breathing in each of the additional postures (supine, left recumbent, right recumbent, sitting and standing) will be collected. If the early respiratory maneuver were done in a sitting position, it can be eliminate from this section of tests.

•Exercise
Subjects will perform a six minute walk to increase their respiratory rate, after which an additional 3 minutes of breathing will be recorded. Walk distance does not need to be recorded.

On completion of the respiratory maneuvers the Holter will be reviewed to ensure the patient did not experience any arrhythmia while undergoing the breathing exercises.

Study burden and risks

The potential risks to a subject participating in this study are believed to be minimal. A subject may feel discomfort, dizziness or shortness of breath during the maneuvers or experience skin reactions due to the application of the Holter electrodes or MediByte device. There is also a possibility that during the respiratory maneuvers study visit the patient may experience an arrhythmia which would not be captured on the Reveal ICM.

There may be additional risks related to study participation that are unknown at this time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Subject is implanted with a Reveal ICM or Reveal XT ICM for unexplained syncope or suspected arrhythmia
Subject (or the legal representative) is willing to sign informed consent form
Subject is 18 years or older

Exclusion criteria

Significant respiratory diseases such as COPD or pulmonary hypertension.
Patients with frequent arrhythmias, including PVC*s.
Patients with known heart failure.
Body conditions that would complicate accurate measurement of respiratory rate with the MediByte device
Patients which are not able to take the postures as necessary for the study protocol and which cannot walk continuously for a period of 6 minutes
Pregnant or breastfeeding women, or women of child bearing potential and who are not on a reliable form of birth control
Subject is enrolled in one or more concurrent studies that would confound the results of this

study

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

Date:	01-08-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL44914.100.13