Evaluation of ReDS Pro System V2.7 and ReDS ICU in patients with heart failure

Dansk titel:

Klinisk evaluering af ReDS Pro System V2.7 og ReDS ICU til måling af lunge væske hos patienter med hjertesvigt

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ABBREVIATIONS

BMI = body mass index
BP = blood pressure
CI = cardiac index
CO = cardiac output
dPAP = diastolic pulmonary artery pressure
ECG = electrocardiography
HF = heart failure
HR = heart rate
ICD = implantable cardioverter defibrillator
ICU = intensive care unit
LVEF = left ventricular ejection fraction
mPAP = mean pulmonary artery pressure
NYHA = New York Heart Association
PAPi = pulmonary artery pulsatility index
PEEP = positive end-expiratory pressure
PCWP = pulmonary capillary wedge pressure
ReDS = remote dielectric sensing
SAT = saturation

2. Description and classification of the device (ReDS Pro System V2.7 and ReDS ICU)

The Remote Dielectric Sensing (ReDS) System is a non-invasive device that includes two sensors and a bedside console, and it is designed for the measurement of lung fluid using extremely low power electromagnetic waves. Fluid readings are displayed in volume percentage units. The ReDS Pro System V2.7 system has CE approval (3900874CE01) and FDA clearance. The Bedside Console consists of an embedded computer with a touch-screen display. The device is managed by computer software, which analyzes the measured signals and displays the measurement results. The console includes an electronic module and a wireless communications module. The system is portable, available at the patient's bedside and is AC-powered from a standard wall electrical outlet. The Sensor Unit is applied and positioned on the patient thorax according to anatomical markers over the patient clothes. The ReDS readings are stored locally on the device without any patient identifiers.

The ReDS ICU configuration is intended to allow continuous monitoring in the ICU setting, and except from the following main modifications the configuration is identical to the CE-marked ReDS Pro System V2.7 device: the sensors are converted to low-profile adhesive patch-sensors that are attached using standard biocompatible tape to the patient's skin for 48 hours in ICU setting. The sensors are disposable and intended for single-patient use. Cables can be detached and reattached by connectivity ports along the cable to support sensors replacement. A small tiltmeter to track chest sensor's orientation was added to support recording of postures. Additionally, the system software has been updated to support continuous monitoring.

The ReDS ICU configuration is intended for an observational study in the ICU setting. No immediate or long-term risks are anticipated. In both configurations, the ReDS system is non-invasive and uses radiofrequency waves at a power level, which is more than 200 times below the level that requires testing (i.e. exemption level) according to SAR safety (FCC and European regulations) and below 60601-1-2 emission limits. The system uses a low-voltage DC medical power supply and conforms to medical electrical safety standards. The adaptations to the sensors preserve the safety features of the tested version and can therefore be considered safe. The sensors were tested for safety, and the results met the required criteria. The software changes support continuous measurement and are not expected to introduce any safety risk. The patches are attached to the patient skin by a 3M medical transfer tape approved for its biocompatibility when adhered to the skin. We will monitor patient skin periodically for any irritation that may be caused by the tape or by the back sensor due to continuous use. The ReDS System will be used under supervision of a trained operator.

Based on the above, we summarize that except for above detailed modifications the ReDS ICU system is identical to the CE-marked ReDS V2.7 certified version and is safe to use in this observational clinical study.

3. Information on the Manufacturer

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https://sensible-medical.com/

Manufacturer Statement of Compliance for Investigational Device
Manufacturer: Sensible Medical Innovations LTD.
Medical device under investigation: ReDS Pro System V2.7
Clinical investigation plan title: Evaluation of ReDS v2.7 and ReDS ICU in patients with heart failure
Clinical investigation reference no. / ID no.:
The manufacturer of the above investigational device hereby confirms that the investigational device in question conforms to the applicable essential requirements set out in Directive 93/42/EEC on medical devices, apart from the aspects covered by the clinical investigation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subjects. This includes, where appropriate, technical and biological safety testing and pre-clinical evaluation, as well as provisions in the field of occupational safety and accident prevention, taking into consideration the state of the art;

Manufacturer: Sensible Medical Innovations LTD.
Medical device under investigation: ReDS ICU System
Clinical investigation plan title: Evaluation of ReDS v2.7 and ReDS ICU in patients with heart failure
Clinical investigation reference no. / ID no.:
The manufacturer of the above investigational device hereby confirms that the investigational device in question is based on the CE marked device (ReDS Pro System V2.7), using the same bedside console configuration which includes main electronics, power components and software. The main modification includes replacing the applied non-contact sensors used for spot measurements, with slim skin-patches sensors design which are single-patient-use and utilized for monitoring patients inside the ICU under the supervision of a trained professional during an observational study. An assessment of the safety implications of the modifications has been performed. Instructions for use and testing were adapted accordingly. Hence, device modifications related to the clinical study in the ICU do not raise any issue of electrical safety or biocompatibility. Other risks specific for the use in ICU will be monitored, assessed, and reported in accordance with GCP requirements. The manufacturer declares that the noted device is safe for use as an investigational device in an observational clinical study in Rigshospitalet Hospital, Copenhagen, Denmark. For detailed comparison to the CE marked device see investigator brochure.

4. PURPOSE

Over the last 30 years, the prognosis for patients with systolic heart failure (HF) has improved significantly, including prolonged life-expectancy, due to pharmacological treatments and cardiac devices (1). Despite these improvements in treatment, HF remains a major cause of morbidity and mortality, with almost 1 million patients admitted for HF annually in the United States (2), and the 5-years mortality rate remains near 50% (3). Although, the rates of HF hospitalization have decreased by nearly 30% during the past decade (4), there has not been any reduction in readmission after HF hospitalization. Thus, the latest studies show that HF readmission rates range between 19%-31% at 30 days (5) and around 50% at 6 months (6).
Re-hospitalization in patients with HF is often due to excess lung fluid and congestion (7). Prevention of HF hospitalization is important as it may lead to excess mortality and is an additional economic burden for the community (8). Early identification of subclinical congestion may prevent some HF exacerbation (9). Studies have reported that early detection of lung impending volume overload by pulmonary artery pressure guided therapy (e.g. CardioMEMS) in patients with HF is effective on patient behavior (e.g. medicine compliance) and adjusting pharmacological therapy to avoid re-hospitalization (10,11).

Continuously hemodynamic monitoring is essential in critically ill patients in an intensive care unit (ICU) who requires vasopressor, vasodilator and inotropic therapy (12). Right heart catheterization (e.g. Swan-Ganz) is the gold standard of hemodynamic monitoring but it is invasive and costly.
ReDS is a non-invasive device designed for quantifying lung fluid using low power electromagnetic waves. Studies has described the potential of ReDS to be used to track fluid status and guide medical management in HF patients (13,14). Furthermore, it has been reported that ReDS measurements of lung fluid is significantly associated with findings on chest computed tomography (CT) (14,15) and highly correlated to measures obtained through right heart catheterization (16). However, description of the feasibility and evaluation of ReDS ICU measurements of lung fluid in HF patients in ICU settings have not been studied before. There is a need for studies exploring non-invasive approaches of continuous hemodynamic monitoring to have alternatives to the invasive methods currently available.
We hypothesize that ReDS 2.7 allows for the identification of pulmonary congestion in out-patients before they develop symptomatic HF exacerbation and that the meassurements are correlatated with the CardioMEMS measurements. The aim of the out-patient part of the trial is to evaluate ReDS V2.7 efficacy in measuring lung fluid compared to pulmonary artery pressure guided therapy (CardioMEMS) in HF patients in the outpatient clinic under article 82 of the medical device regulation. The CardioMEMS HF System is CE marked and currently used in clinical practice at specialized hospitals in Denmark in patients with HF and NYHA functional class III.
We hypothesize that ReDS ICU allows for hemodynamic monitoring of ICU-patients continuously and that ReDS ICU provides hemodynamic measuremenst that are highly correlated with the Swan-Ganz meassurements. We expect that changes to upper body-position will not affect the fluid parameter measured by ReDS ICU while the raised leg test, which increases the preload, will increase the fluid parameter measured by ReDS ICU. The aim of the ICU-patient part of the trial is to evaluate the feasibility of ReDS ICU system in critical-ill patients in an ICU setting under article 82 of the medical device regulation.
ReDS Pro System V2.7 and ReDS ICU are the same system, as described in the investigators brochure with only minor modifications (Appendix 02.02b). For the ReDS Pro System V.2.7, we will conduct an investigator-initiated study of already CE approved medical advice and for the ReDS ICU System we will test this prototype without the intention of obtaining CE-approval.

5. METHODS

The study is an investigator-initiated, prospective cohort, single site study. The study has two parts: one for ICU patients and one for out-patient clinic patients. The study will take approximately 21 months to complete. Inclusion is expected to run from May the 1st, 2022 or as soon as possible thereafter and will continue until 10 patients have been included in out-patient part and 15 patients in the ICU part. The inclusion period is expected to be 21 months.

In the ICU study, the patient will have a Swan-Ganz catheter and an arterial catheter inserted as part of standard clinical practice and transthoracic echocardiography is likewise routinely performed. If the patient is eligible and after giving informed consent, the ReDS ICU system is applied for 48 hours continuously monitoring, whereafter it will be removed, and the patient's participation in the study is completed. During the inclusion in the study, the following data will be recorded:

1) Body position (Upper body elevation, left or right recumbent position)
2) ReDS ICU Lung Fluid parameter

3) ReDS ICU tilt parameter
4) Changes in patient body position

Before initiating the following interventions, the patient is required to have been hemodynamic stable for at least 1 hour, with a mean arterial pressure (MAP) around 65 mmHg and a maximum fluctuation of vasopressor-need of 25%. During the 48 monitoring, the following tests will be done:

1) Raised leg test – Both legs raised to 45° for 10 minutes.
2) Upper body elevation test - Starting from 30° the upper body is elevated to 45° then back to 30°, then 15° and back to 30°.
3) Left and right lateral recumbent position to 15° test – First left lateral recumbent position for 10 minutes then back to supine, then right lateral recumbent position for 10 minutes and then back to supine.
4) PEEP test – 5 cmH_2O increase PEEP for 10 minutes.

For all interventions, changes in HR, MAP, dPAP, mPAP, CO, SAT and ReDS ICU parameters (tilt and lung fluid) will be recorded 10 minutes prior, during and 10 minutes following completion of each test (1-4) . The completion of all interventions is estimated to take about 3 hours. The intervention will be paused if necessary.

In the out-patient part, if the patient is eligible and provides informed consent, the patient will have 4 measurements of lung fluid, which will be done as home-visits by a study designated healthcare worker. The first visit will be after inclusion and the following visits will be 14 (+/-5) days, 28 (+/-5) days and 42 (+/-5) days after the first visit.

The visits are expected to take no more than 1 hour each. During each visit the following data will be recorded:

1) Height (only recorded at first visit) and weight (recorded each visit)
2) NYHA functional class
3) Presence of peripheral oedema
4) Orthopnea
5) Rales by auscultation
6) CardioMEMS measures
7) ReDS v2.7 measures lung fluid parameter

Endpoints

Primary endpoints

ICU part:

- Correlation between ReDS ICU fluid parameters and Swan-Ganz measurements including right atrial pressure, pulmonary wedge pressure, mPAP and dPAP.

Out-patient part:

- Correlation between ReDS v2.7 fluid parameters and CardioMEMS measurements

Secondary endpoints

ICU part

- Changes in ReDS ICU fluid parameters following changes in Positive End Expiratory Pressure.
- Changes in ReDS ICU fluid parameters following raised leg test.
- Changes in ReDS ICU fluid parameters following changes in body position.
- Changes in ReDS ICU fluid parameters following changes administration of diuretics and inotropic/inodilators

Out-patient part

- Correlation between ReDS v2.7 fluid parameters and body weight
- Correlation between ReDS v2.7 fluid parameters and CardioMEMs measure
- Correlation between ReDS v2.7 fluid parameters and dyspnea symptom evaluated by NYHA class.

SAFETY

Safety assessments will consist of registration and recording of adverse events (AEs), adverce device effects (ADEs), Serious Adverse Events (SAEs) and Serious Adverse Device Effects (SADEs). AEs, ADEs, SAEs and SADEs will be recorded during ReDS Pro System v2.7 and ReDS ICU monitoring time.
The following adverse device events (ADE) can be expected from both devices: Localized rash and redness of the skin.
Regarding, SAEs: The population of interest is vulnerable, and hospitalizations, prolonged ICU stay (ICU part), changes to medical therapy and death are considered likely.
Specifically trained medical personnel will be present during the study visits and secure adequate assessment of the relevant safety parameters listed above, along with timely and accurate treatment of possible complications to study procedures. If it is medically necessary in the opinion of the investigator or if it is the wish of patients, the patient will be withdrawn from the study. At any time can the patient withdraw from the study. Patients who withdraw from the study will not be replaced by others.

6. STATISTICAL CONSIDERATIONS

At the Heart Center ICU, Rigshospitalet, 20-40 patients with HF is admitted monthly from this patient population, 5-10 will require Swan Ganz monitoring and will eligible for the present study.

Around 30 patients have a CardioMEMS sensor implanted and are followed at the out-patient HF clinic at Rigshospitalet.
For this pilot study, we estimate that 15 patients in the ICU part and 10 patients in the out-patient part will be sufficient to evaluate the feasibility of the ReDs systems.

7. PARTICIPANTS

ICU part

Inclusion criteria:

- at least 18 years of age
- hospitalized in ICU setting at Rigshospitalet
- intubated
- unconscious or sedated (Glasgow Coma Score <8)
- monitored using Swan-Ganz and arterial catherization.

Exclusion criteria:

- pacemaker or ICD

- congenital heart malformations or intra-thoracic mass that would affect the right lung anatomy (e.g. dextrocardia, lung carcinoma)
- wounds, burns, healing tissue, skin infection or recent skin graft or flap where the sensors should be attached to the skin
- habitus is out of range due to one or more of the following
- height less than 155 cm or higher than 195 cm
- estimated BMI of less than 22 or more than 36
- standard active therapy has been stopped as the patient is inevitably dying.

Out-patient part

Inclusion criteria:

1) at least 18 years of age
2) history of Chronic heart failure > 3 months
3) CardioMEMS

Exclusion criteria:

1) pacemaker or ICD on the right side
2) congenital heart malformations or intra-thoracic mass that would affect the right lung anatomy (e.g. dextrocardia, lung carcinoma)
3) wounds, burns, healing tissue, skin infection or recent skin graft or flap where the sensors should be attached to the skin
4) habitus is out of range due to one or more of the following
    a. Height less than 155 cm or higher than 195 cm
    b. BMI of less than 22 or more than 38
        i. For BMI 36 to 38, chest size ruler should be 39 or less
5) cancer or other severe non-cardiac disease with estimated life expectancy less than 1 year
6) planned hospitalization for ICD, pacemaker, lung or heart surgery including heart transplantation during the study period.

8. RISKS, SIDE EFFECTS AND SHORT-TERM AND LONG-TERM INCONVENIENCES

The ReDS System will be used in accordance with the manufacturers instruction and be operated by trained healthcare workers. Operator will be monitoring patients' skin for any side effects of sensor interaction like redness. Sensors will be removed if any sensor interaction is observed. No additional risks and long-term inconveniences are expected. However, unknown side effects or risks associated with the study program cannot be ruled-out.

9. BIOLOGICAL MATERIAL

No biological material will be collected in the study.

10. DATA FROM MEDICAL JOURNALS

The following data will be collected from medical records after informed consent:

ICU part

1) Patients demographics
2) Contact information
3) Comorbidities
4) Actual medical therapy
5) ECG monitoring (HR, arrythmias)
6) Standard biochemistry (including hemoglobin, creatinine, BNP, electrolytes)
7) Systolic, diastolic and mean arterial pressure from arterial catheter
8) Urine output
9) Time and dose of all vasoactive and diuretic
10) Fluid administration
11) Dialysis
12) Netto fluid in/output.
13) Central venous pressure
14) Swan Ganz measurements: dPAP, mPAP, CO, CI, PAWP.
15) Changes in respiratory ventilation settings
16) Saturation from periphery pulse oximetry
17) Central venous oxygenation
18) Transthoracic echocardiography for evaluation of LVEF.

Out-patient part

1) Patients age
2) Comorbidities (only recorded at first visit)
3) Actual medical therapy
4) Hospitalization the past 90 days including diagnosis
5) CardioMEMS measures

11. HANDLING OF PERSONAL DATA

All data is processed and stored confidentially, and personal data will always be handled in accordance with the Danish Data Protection Act and the General Data Protection Regulation. Source data will be recorded in the electronic patient record or on specific worksheets. Fluid parameters in the ReDS systems are stored pseudo-anonymously on the device and are then moved to a secure database (Loggede Data). The ReDS-systems will be kept offline and therefor the ReDS reading will not be sent to a cloud as indicated in the instruction for use (02.02b). The ReDS systems are stored in a locked and secure room at Rigshospitalet. An electronic Case Report Form (eCRF) will be constructed for data capture. Data are stored pseudo-anonymously in a separate approved and secure database (Capital Region RedCap), which only the doctors, research assistants and project nurses of the trial will access using person-specific log-in and password. A study idis used as patient identification in the RedCap database. The key linking the study-id with the personal id is kept separately from the study data with limited access controlled by the study investigator or designee. Authority and obligations are documented in the log of delegation of responsibility in the trial. The

investigators are responsible for ensuring the accuracy, completeness, legibility and timeliness of the data recorded in the eCRFs.
The informed consent gives the investigator and possibly control authority direct access to data from the patient's journal. These are used to view information on the participant's medical condition necessary for the conduct of the trial and for self-control, quality control and monitoring. The data can be used for supplementary scientific purposes, educational purposes and publication.
The trial will be reported to the Knowledge Centre on Data Protection Compliance in the Capital Region and will not be initiated before it is approved. The study database will be maintained for 10 years after completion of the study after which the data will be deleted.

12. ECONOMY

The project is carried out on the initiative of Christian Hassager. The study is independent of commercial interests and external sponsors will have no influence on the conduct of the study. The investigators have no financial or other connection with the granting authority or Sensible Medical.

13. COMPENSATION TO PARTICIPANTS

Reimbursment will not be given.

14. RECRUITMENT OF PARTICIPANTS AND INFORMED CONSENT

For the ICU part, eligible patients are unconscious and accordingly not able to provide informed consent. Therefore, informed content will be obtained from an independent guardian and a close relative according to Medical Device Regulation (MDR) article 64. The independent guardian will be a physician at Rigshospitalet without treatment responsibility for the patient. The guardian will be independent of the investigator's interest and without interest in the study. Based on all available knowledge of the patient and the study, the guardian will decide whether it is justifiable for the patient to participate in the study.

Informed consent will be obtained from the nearest relatives in accordance with MDR article 64 prior to patient inclusion. The first contact to the nearest relatives will be at the ICU department or by telephone if the relatives have already informed the ICU department that they are not planning to visit the patient within the next 12 hours. Before the study information is presented to the relatives, they will be informed that it is an inquiry about participation in a medical health science project from the treating team at the ICU. The relatives will be informed that they can bring an assessor. Further, they will be informed that they will be given the time needed for consideration before signing the informed consent following the meeting. The information will be provided in a quiet, designated room close to the ICU department. The information is given by a doctor from the ICU department or by the investigators or designee. The nearest relatives will be given written and oral information about the study and encouraged to ask questions. The relatives or the patient will be informed of the possibility of receiving information about the study results and new health information and the possibility of declining this on the informed consent. As this part of the study is in unconscious patients, the usual 24 hours considerations time will be shorter, if and only if the relatives accept. This is due to logistical issues otherwise difficult to accomplish in the short time window of one to two days where the patient fulfilled the inclusion and none of the exclusion criteria. A minimum of 3 hours considerations time will be given.

Patients are informed that the document "Participants rights in health research projects" are enclosed with the written information.

If a patient regains before initation of monitoring, they no longer fulfill the inclusion criteria and are no longer a candidate for the study. If the patient regains consciousness following the end of the monitoring period, they will be asked for informed consent and participant information. If patients are not interested in participation all data recorded will be deleted.

For the out-patient part, potentially eligible participants will be identified during planned outpatient appointments in the HF clinic by the treating HF specialist. The treating HF specialist will ask if the patient would like to have more information on the study. If the patient is interested, the patient will receive the written participant information and "Participants rights in health research projects". The investigator or delegate will then contact the patient either at the hospital or over the telephone to arrange a meeting with the patient. The patient will be informed of the right to bring an assessor and 24-hour deliberation time. The assesor can be present physically or electronically through audio/video connection. At the meeting the investigator or delegate will provide information about the study after which the participant has a minimum of 24 hours to consider their participation. If needed, a meeting will be for signing the informed consent.

15. PUBLICATION

Results, positive, negative, or inconclusive, will be published in international medical journals. The trial will be registered at https://clinicaltrials.gov. Additionally, the results will be presented at national and international congresses. The participants will not be identifiable in any reports or publications.

16. ETHICAL CONSIDERATIONS

This clinical trial complies with the Declaration of Helsinki, modified by the 64th World Congress in Fortaleza, Brazil in 2013.

The planned examinations in outpatient-part and ICU-part are all considered very low-risk procedures. All planned examinations in the ICU part, except for the fluid parameter measures from the ReDS system, are part of the routine work-up of patients in an ICU setting. The planned experimental design with different body positions during ICU care is considered very low risk with no expectation of harm or long-term inconveniences. All planned examinations in the out-patient part except for the ReDS fluid parameter are all standard HF care. The CardioMEMS sensor is CE marked and currently used in clinical practice in selected patients with chronic HF. The ReDS system is CE marked for the out-patient fluid parameter measures.

The participants are not expected to benefit directly from their participation in the study. The knowledge obtained by this study may contribute to a future reduction in hospitalizations for chronic HF patients by the non-invasive use of the ReDS system. If the ReDS ICU systems proves feasible in an ICU setting, this could help guide physicians for treatment of the critical-ill patients and hopefully reduce the length of stay at the ICU and mortality. We believe that the potential gain from the studies is greater than the risks that the participants are exposed to.

17. INSURANCE

Patients are covered by the Patient Compensation Association

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