WEAN SAFE

Frequently Asked Questions

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Part 1: General Questions

Q1: What is WEAN SAFE?

A: WEAN SAFE (WorldwidE AssessmeNt of Separation of pAtients From ventilatory assistancE) is a multi-centre, prospective, observational, 4-week inception cohort study being carried out by the Acute Respiratory Failure section of ESICM. Weaning from assisted ventilation represents a challenge for intensivists and patients spend a considerable amount of time in being liberated from mechanical ventilation. While guidelines do exist on the classification of weaning, a recent study has shown that these may not be applicable to all patients. Moreover, different practices exist in regard to weaning procedures. WEAN SAFE will prospectively assess the burden of, management and spectrum of approaches to weaning from ventilation, in patients that require invasive mechanical ventilation for any reason, for a time period of at least 24 hours.

Q2: Why is this study being conducted?

A: The purpose of this study is to describe, in a large population of ICU patients the burden of, management and spectrum of approaches to weaning from ventilation, in patients that require invasive mechanical ventilation for any reason, for a time period of at least 24 hours. It will answer the following questions:

- What are the current approaches taken to wean patients from invasive mechanical ventilation?
- What is the frequency of delayed weaning from invasive mechanical ventilation?
- What are the factors that are used to determine when patients are in the weaning phase?
- What are the barriers to effective weaning from invasive mechanical ventilation?
- What factors (patient, institutional, medical practice) contribute to failed attempts to wean from invasive mechanical ventilation?
- What is the impact of premorbid conditions on weaning from invasive mechanical ventilation?
- What is the utility of existing classifications for weaning from invasive mechanical ventilation?
- What is the impact of early versus delayed and/or failed weaning from invasive mechanical ventilation?

Q3: When is the study being performed?
A: The study enrollment period will commence on October 1st 2017 and will end on March 31st 2018. ICUs are required to recruit patients to WEAN SAFE during any 4 consecutive weeks within this window.

Q4: Do I need IRB approval?
A: As this is a prospective observational study, and not an interventional study, ethical committee approval may or may not be required depending on what country your ICU is located. IRB approval must be obtained for each center if required by its local regulations. You must check with your local ethical committee as to whether approval is required. In most countries, a National coordinator will liaise with participating centers, helping you to obtain IRB approval.

Q5: Can you send me the IRB approval from the Coordinating Center?
A: We do not have a "global" Coordinating Center for this study. Normally, each country has one National Coordinating Center, depending on each country's regulations.

Q6: Does this study require informed consent?
A: This is an observational study, and for it to yield useful information, we must be able to include all patients in ICU during the recruitment window if they fulfill the criteria. Requiring informed patient consent makes this very difficult. Ethical committees are generally aware of this issue, and will frequently waive consent for an observational study such as this.

Q7: Are you able to help with ethics committee submission fees?
A: Unfortunately, we do not have funds for ethics committee applications at this stage. This might change in the future, but this is the situation at the moment.

Q8: Is there any financial compensation?
A: No. Participation in the trial is completely voluntary. This study will provide important data on the management and impact of weaning from assisted mechanical ventilation in patients.

Q9: What about authorship?
A: Results from the trial will be published by the WEAN SAFE nominated Executive Committee. Each participating center and its two lead investigators will be named as collaborators on the published manuscript. In addition, the top 2 recruiting countries (normalized by population), and the top 2 recruiting countries (absolute value) will be invited to participate in manuscript drafting and offered authorship.

Q10: How will the data be managed?
A: All data will be anonymized and cannot be linked to individual subjects. The data will be stored securely on the servers of CLINFILE® and all procedures regarding data management will comply with the EU directive on data protection 95/46/EC. For more details, please see the data management file for WEAN SAFE, which outlines the processes to be used. In addition, please see a letter from CLINFILE®, the data management company assisting us with this study.

Q11: Who owns and can access the collected data?
A: The data is owned collectively by the 'WEAN SAFE investigators'. Individual site data will be co-owned by each participating centre, and they will be given access to this data for any scientific purpose upon request to the WEAN SAFE Principal Investigators. For more details, please see a letter from Dr.'s Laffey and Bellani, the WEAN SAFE PI's, regarding access to the data.

Q12: Can you share country-specific data with a National Society after the study is complete?
A: Yes. The WEAN SAFE Principal Investigators would require a formal letter from the National Society requesting access to country specific data through their National Coordinator. Any data provided will be on the condition that the society will ask for permission before publishing any analyses based on this data. Such data would be provided after the main pre-specified analyses have been completed and published.

Q13: Can National Societies endorse WEAN SAFE and how will they be recognized their endorsement and assistance with site recruitment?
A: Yes, endorsement from National societies is strongly encouraged, and will be sought by national coordinators**.** The formal letter of support will be uploaded to the WEAN SAFE webpage on the ESICM website and the National Society will be acknowledged for their support of the study. All national society endorsements will be acknowledged in the major publications and communications (in an appendix) in addition to acknowledgment on the WEAN SAFE webpage.

Q14: How do I participate?
A: Intensive Care Units of all sizes in all geographical locations around the world are required. Register your interest here any time until February 2018. (Please note that the form that was previously being used has been disabled.)

Q15: I have submitted my expression of interest, but I did not receive a confirmation email.
A: Please make sure that you have checked your junk folder in case the email was sent there directly. If you continue experiencing difficulties, please contact research@esicm.org.

Q16: Do you have any tips on how to recruit sites while I wait for endorsement from National Societies?
A: One suggestion would be to start using your "personal" contacts or to ask for support from your national ESICM representative. However, if it is more appropriate to wait and have official endorsement by National Societies, there will still be time before the enrollment of patients begins (in October 2017 and continues until March 2018)!

Q17: Will the ESICM provide support for WEAN SAFE, similar to LUNG SAFE?
A: ESICM has committed to support WEAN SAFE, and has endorsed participation. This is an ESICM Trials group study.

Part 2: Questions regarding the electronic Case Report Form (eCRF)

Q1: How will the data be exchanged?
A: Data will be inputted directly into the e-CRF by all investigators.

Q2: Does the information need to be collected in real time seven days a week?
A: Data do not need to be entered into the eCRF in "real time", but can be added "in batches" when convenient for the investigators (e.g. even once a week, provided that clinical data is accessible). As this is an observational study, only the variables that are recorded for clinical purposes will be entered on the eCRF.

Q3: Where will the data collected using the eCRF be housed?
A: The data will be housed on the servers of CLINFILE, which is based in France (2 Rue Kellermann, 59100 Roubaix, France, +33 9 72 10 10 07).

Q4: How do I access the eCRF?
A: The eCRF is not yet available. Each site coordinator will be issued a login and password to access the eCRF on CLINFILE's website. A copy of the paper CRF can be downloaded through the ESICM WEAN SAFE webpage.

Part 3: Questions for Site Coordinators

Q1: How/where will the report be disseminated?
A: Results from the trial will be published by the WEAN SAFE-nominated Writing Committee. Each participating center with its two lead investigators and national societies/networks actively supporting the study will be named as collaborators on the published manuscript.

Q2: Will we use hospital data or patient referrals to evaluate the status at D90?
A: The status will be collected for the last time at D90 or upon hospital discharge, whichever comes first, so there is no need to contact the patients after they are discharged from the hospital.

Q3: Is there a maximum number of days on which form 2 would be completed (i.e. if patient is on invasive MV for 40 days or longer, would form be completed every day)?
A: We are asking that form 2 continues to be filled out daily until (a) separation from MV; or (b) day 90 in patients still receiving MV in the ICU. We realize this is a big ask, but the number of patients that will remain on assisted ventilation for prolonged time periods will be low, and it is vital that we get this information for our study.

Q4: Does the site enrolment period last for a maximum of four weeks before it is finished?
A: All patients admitted to your ICU during the 4 week enrollment period that you choose will be eligible for enrollment. Patients that fulfill the recruitment criteria will then be followed for up to 90 days (or until hospital discharge if sooner) after they were first enrolled in the study.

Q5: For all patients enrolled during the one month period, if any of those are still present in ICU at the end of the month, do we continue collecting data daily until they are discharged from ICU or deceased? And then follow up their date of hospital discharge or 90 day outcome later?
A: Patients admitted to the ICU during the enrollment period, even if they are still in the ICU at the end of the one month period, need to be followed up daily until ICU discharge or death. For all patients, the hospital or 90 day outcome is collected, whichever comes first (i.e. if they are discharged from hospital before day 90, this is the end of data collection).

Q6: Can sites choose the four week period to collect data?
A: Yes, sites can choose any four week period to recruit patients as long as it falls within the overall study period from October 1, 2017 – March 31, 2018.

Q7: Can you explain how the data sharing agreement will work? With whom does each institution form an agreement?
A: The data use/transfer agreement will be formed between the institution that requests it and the European Society of Intensive Care Medicine. If you have a data use agreement template, Guy Francois would be happy to review and sign it.

Q8: If the patient is already participating in another study on weaning or ventilation, shall I exclude those patients from participating in WEAN SAFE?
A: It is not necessary to exclude any patients because they are participating in another similar study, but it is necessary to make note of their participation in another study on the eCRF. There will be a field on the eCRF in which to record other study participation.

Q9: The inclusion criteria states that: "A patient will be included if he/she is undergoing invasive MV on the second morning (between 6am and 10am) after initiation of MV or after ICU admission (if ventilation was already in place at time of ICU admission)". **In the second situation (after ICU admission if ventilation was already in place at time of ICU admission), what is considered day 1 for filling out the CRF? For instance, if the patient started MV in the ER two days before being transferred to the ICU, what will be considered day 1?** There are a high percentage of patients that have started MV before admission to the ICU (in the post-operative room or the ER) while waiting for a bed to be transferred to the ICU.
A: In such a situation, data collection using the eCRF (screening day 1) begins on the day the patient is admitted to the ICU (first day of MV in the present ICU). From that date, all the following dates on which data must be collected are automatically calculated.