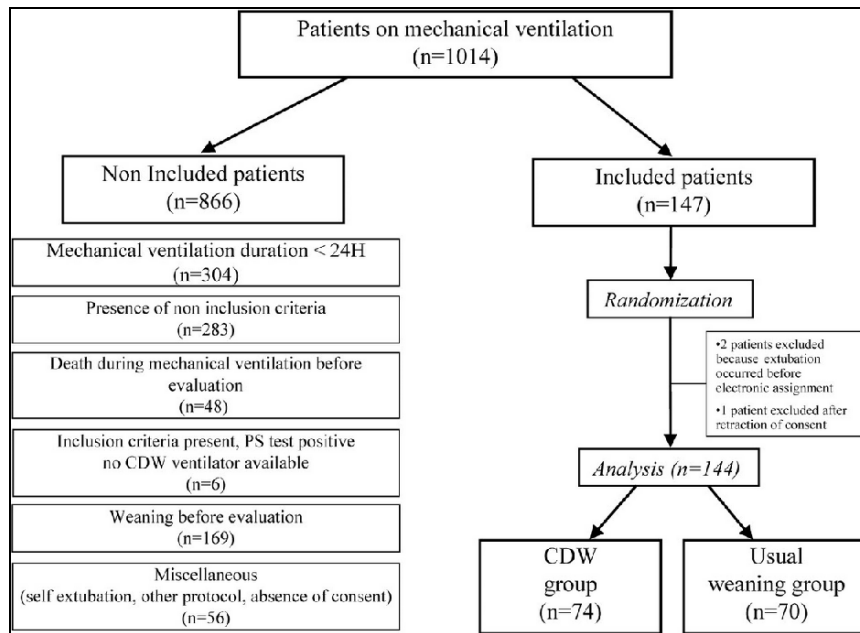## Recording of all patients that are on mechanical ventilation > 24 hours

For later publication, it is important to register all screened patients in the database. In other words: <u>all patients that are on mechanical ventilation longer than 24 hours should be registered</u>. A typical flow chart from a published study shows specific information about the patients that have not been included - look at the picture below (left row):


```
                    Patients on mechanical ventilation
                              (n=1014)

   Non Included patients              Included patients
         (n=866)                          (n=147)

 Mechanical ventilation duration < 24H    Randomization
         (n=304)
                                    •2 patients excluded
 Presence of non inclusion criteria   because extubation
         (n=283)                      occurred before
                                      electronic assignment
 Death during mechanical ventilation before
         evaluation                   •1 patient excluded after
         (n=48)                       retraction of consent

 Inclusion criteria present, PS test positive
 no CDW ventilator available          Analysis (n=144)
         (n=6)

 Weaning before evaluation
         (n=169)                   CDW          Usual
                                   group      weaning group
 Miscellaneous                     (n=74)       (n=70)
(self extubation, other protocol, absence of consent)
         (n=56)
```

Lellouche et al.; A multicenter randomized trial of computer-driven protocolized weaning from mechanical ventilation.
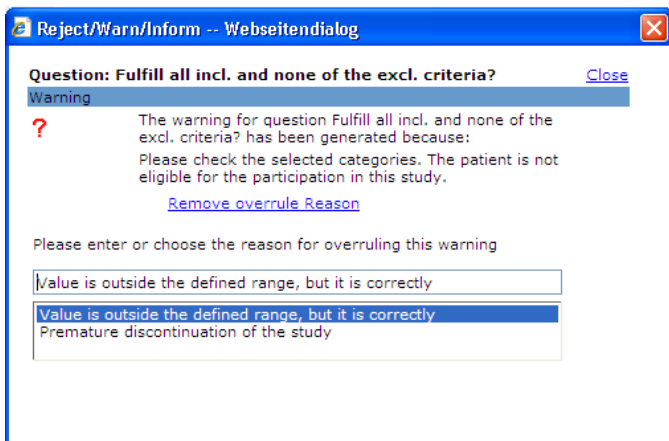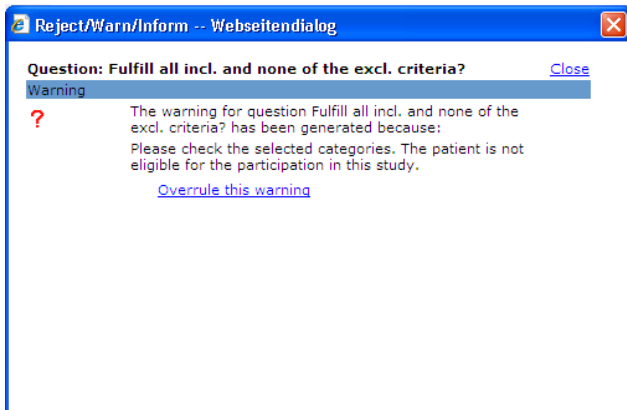
Am J Respir Crit Care Med. 2006 Oct 15;174(8):894-900.

For the VIPS Trial, we want to know how many patients have been ventilated for more than 24 hours, which of inclusion/exclusion criteria have been met..

Practical procedure:

You open up the macro database and create a new subject. Enter the required data as usual up to the "Inclusion/Exclusion criteria".

If one of the inclusion or exclusion criteria is not fulfilled - you get a warning - but then you have to confirm "Overrule this warning" and "Value is outside the defined range but it is correct" and press "Close"

Reject/Warn/Inform -- Webseitendialog

Question: Fulfill all incl. and none of the excl. criteria?   Close

Warning

?   The warning for question Fulfill all incl. and none of the excl. criteria? has been generated because:

Please check the selected categories. The patient is not eligible for the participation in this study.

Overrule this warning

Reject/Warn/Inform -- Webseitendialog

Question: Fulfill all incl. and none of the excl. criteria?   Close

Warning

?   The warning for question Fulfill all incl. and none of the excl. criteria? has been generated because:

Please check the selected categories. The patient is not eligible for the participation in this study.

Remove overrule Reason

Please enter or choose the reason for overruling this warning

| Value is outside the defined range, but it is correctly |

| Value is outside the defined range, but it is correctly |
| Premature discontinuation of the study |

The Patient fulfill all inclusion and none of the exclusion criteria?   ○ no   ⊘

If no, please fill in the eForm "Study Completion"!   ○ yes   *Automatic entry by the database if all required values are known!*

When you go to the next Form ➡ , you will be directed to "Study completion"

Study Completion

Date of last contact with subject: ☐
dd/mm/yyyy

Did the subject complete the study? ○ no   *If no, please specify the main reason!*
                                    ○ yes

Reason for non-completion before randomization:

○ Withdrawn of patient consent   ↓
○ Not fulfill all inclusion or fulfill one of the exclusion criteria
○ Death
○ Other

If the reason is death or other, please make further diclosures in the lower range of this eForm!

Reason for non-completion after randomization:

○ Withdrawn of patient consent   ↓
○ Lost to follow up
○ Appearance of an intolerable AE
○ Death
○ Other

Here you can finish the patient's dataset. The patient has now been entered in the database but as he doesn't fulfill the inclusion/exclusion criteria the dataset is complete.