

# Stress Ulcer Prophylaxis in the Intensive Care Unit

# Information for clinicians

Your department enrols patients in the SUP-ICU trial

The SUP-ICU trial compares pantoprazole and placebo as stress ulcer prophylaxis for critically ill patients

The SUP-ICU trial enrols 3350 patients at intensive care units in Europe

The SUP-ICU trial is supported by governmental funding

The SUP-ICU trial is approved by all relevant authorities

# **Queries? Please contact:**

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# Clinicians' role in SUP-ICU

### Screening

When a patient is admitted to the ICU please screen the patient for inclusion in the trial. If the patient fulfils the inclusion criteria please screen the patient at <a href="www.sup-icu.com">www.sup-icu.com</a>. Even though one or more exclusion criteria are met we kindly ask you to complete the screening procedure.

#### Randomisation

Remember to obtain consent according to your national regulations before randomisation (if required).

Complete the screening procedure. If the patient fulfils the inclusion criteria and no exclusion criteria are met, you will get the opportunity to randomise the patient. Click 'Perform randomisation'. A window with the allocated vial identifier number will appear.



Print or write down the vial identifier number. If you lose the number you can find it in the bottom of the screening form, in an email sent to your email address used for registration or in the trial medication system.

Prescribe the medication in the patient's medication chart/ICU chart as 'SUP-ICU trial medication' intravenously once daily' (if possible). Remember to prescribe the first dose at the time for randomisation.

### **During the ICU stay**

The trial medication is prescribed once daily as long as the patient is admitted to the ICU (maximum 90 days). If the patient is discharged and readmitted to the ICU, please continue the prescription. Aside from trial medication patient management will be otherwise unaffected.

# Information about SUP-ICU

### **Background**

Critically ill patients are at risk of developing gastrointestinal bleeding and stress ulcer prophylaxis (SUP) is recommended. However, the evidence supporting prevention of stress related gastrointestinal bleeding is lacking. Furthermore, research has indicated that SUP may increase the risk of pneumonia, clostridium difficile infection and cardiovascular complications.

The aim of the SUP-ICU trial is to assess benefits and harms of SUP with pantoprazole for adult critically ill patients in the ICU and hereby improve the evidence for the use of SUP.

### Methods

In total 3350 patients in ICUs in Europe will be randomised to receive

#### either

 Pantoprazole 40 mg (added 10 ml of sodium chloride 0.9%)

or

 Placebo (sterile air filled vial added 10 ml sodium chloride 0.9%)

Aside from trial medication patient management will be otherwise unaffected

#### Results

At the end of the trial we will calculate 90 day mortality and the incidence of gastrointestinal bleeding, pneumonia, clostridium difficile infection and cardiovascular complications in the two groups.

#### Funding

The trial has a budget at 17 million Danish kroner (2.3 mil Euro) and is funded by governmental funding (Innovation Fund Denmark)

The full protocol is available at www.sup-icu.com

# **Manuals**

The trial manuals and other relevant documents are available at www.sup-icu.com (Trial documents)

### Queries?

If you have any queries do not hesitate to contact coordinating investigator Søren Marker Jensen. See contact information at the back of this leaflet.

Do you need help?
Call the SUP-ICU Hotline
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Available 24/7
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