Serious adverse reaction (SAR) and

suspected unexpected serious adverse reactions (SUSAR)

**PART 1:** SAR and SUSAR (from investigator to Sponsor)

**PART 2:** SUSARs (Sponsors assessment)

**Protocol title: The Stress Ulcer Prophylaxis in the Intensive Care Unit (SUP-ICU) trial**

EudraCT number: 2015-000318-24

Protocol number: RH-ITA-006

**PART 1 (To be filled in by Investigator)**

**Report date** (dd-mm-yyyy)**:**

**Report type**

Initial  Follow up

**Participant information**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Patient initials | Country | Date of birth (dd-mm-yyyy) | Sex  M  F | Height:  Weight: |
| Trial participant ID | Name of site |

**Serious Adverse Reactions (SARs)**

A SAR is life-threatening, requires hospitalisation or prolongation of existing hospitalisation or results in persistent or significant disability or incapacity. See definition of SARs in the SUP-ICU trial at next page.

If a SAR occurs please remember to

1) discontinue the trial medication

2) continue to fill in day forms

|  |  |
| --- | --- |
| SAR onset date (dd-mm-yyyy) | SAR end date (dd-mm-yyyy) |
| Patient discontinued from study drug due to SAR  Yes  → date (dd-mm-yyyy): time (hh:mm). No | |

|  |  |
| --- | --- |
| **Type of reaction** | **Mark** |
| **Anaphylactic reaction related to the intervention**  *Definition: urticaria and a least one of the following:*  *1. Worsened circulation (>20% decrease in blood pressure or >20% increase in vasopressor dose)*  *2. Increased airway resistance (>20 % increase in the peak pressure on the ventilator)*  *3.Clinical stridor or bronchospasm*  *4.Subsequent treatment with bronchodilators* |  |
| **Agranulocytosis related to the intervention**  *Definition: any new, acute and severe drop in granulocytes to <0.5 x 109/l requiring active monitoring or treatment* |  |
| **Pancytopenia related to the intervention**  *Definition: any new, severe drop in red blood cells, white blood cells and platelets requiring active monitoring or treatment* |  |
| **Acute hepatic failure related to the intervention**  *Definition: severe and progressing acute hepatic failure as judged by the treating doctor or the investigator* |  |
| **Steven-Johnson syndrome and toxic epidermal necrolysis related to the intervention**  *Definition: severe dermatological reaction with a skin biopsy confirming the diagnosis* |  |
| **Interstitial nephritis related to the intervention**  *Definition: nephritis affecting the interstitium of the kidneys surrounding the tubules, with a kidney biopsy confirming the diagnosis* |  |
| **Angioedema – Quincke’s oedema related to the intervention**  *Definition: a vascular reaction involving the deep dermis, subcutaneous or submucosal tissues, resulting in a characteristic localized oedema* |  |
| **Reaction not described above but related to the intervention (unsuspected)** *please specify* |  |

**Evaluation of SAR**

|  |  |  |
| --- | --- | --- |
| **Outcome** |  |  |
| Ongoing reaction |  |  |
| Resolved |  |  |
| Fatal |  |  |
| Unknown |  |  |

**Death**

|  |  |
| --- | --- |
| Date of death (dd-mm-yyyy) | Cause of death |

Relationship of the event and study drug

|  |  |
| --- | --- |
| Unrelated to the study drug  (No, unlikely) | Related to the study drug  (Possible, probable, definite) |

Drug information

|  |  |
| --- | --- |
| Batch no: | Did the reaction abate after discontinuing the trial medication?  Yes  No  NA |

Event Description

Concomitant medication(s) relevant to the event (exclude those used to treat the event)

|  |
| --- |
| Concomitant drug(s) and dates (dd-mm-yyyy) of administration. |

Reporter information Investigator information

|  |  |
| --- | --- |
| Name: | Name: |
| Address: | Address: |
| Phone:  + | Phone:  + |
| Profession: | Profession: |
| Signature & date (dd-mm-yyyy) | Signature & date (dd-mm-yyyy) |

Fill in this form and e-mail it to the coordinating centre

**E-mail:** [contact@sup-icu.com](mailto:contact@sup-icu.com)

Sponsors signature for receiving this report:

Date: \_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PART 2: (To be filled in by sponsor)**

Causality assessment by Sponsor:

**1. Result of causality evaluation**

Not related to study drug (Unlikely/doubtful) → (If not judged related, please comment in box 4)

Related to study drug (Possible/Probable/Definite) → (Go to box 2 below)

**Expectedness** **assessment by Sponsor (only relevant if the SAR is related to the study drug):**

**2. Result of the expectedness evaluation**

Expected (due to relevant reference document)

Unexpected→ (Go to box 3 below)

**Summary:**

**3. Category of event**

SUSAR (SAR is both related and unexpected)

SAR (SAR is related but not unexpected)

**Notify relevant authorities according to protocol**

Sponsors comments (including information regarding unblinding):

**4.**

Sponsors signature:

Date: \_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_