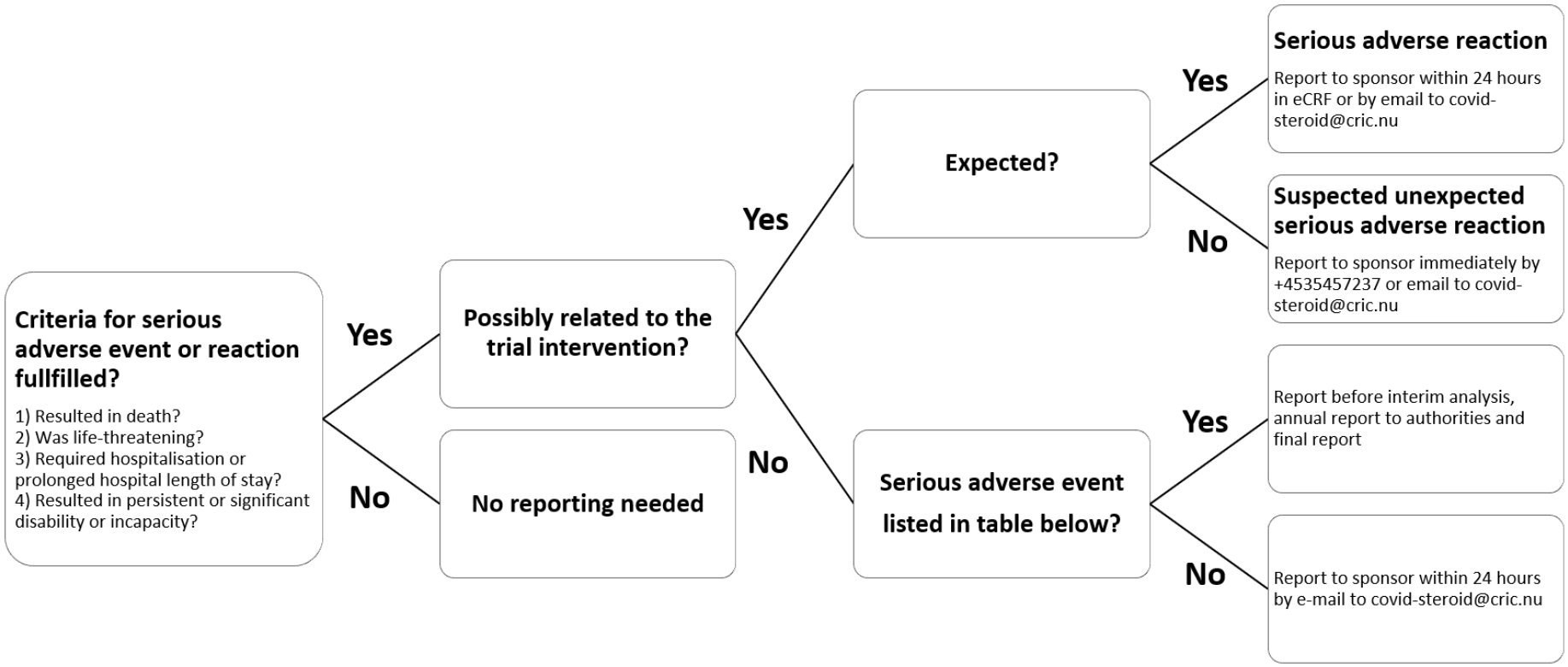
Procedure for reporting serious adverse events and serious adverse reactions from randomisation to day 28 in the COVID STEROID 2 trial

Flow chart for reporting serious adverse event (SAEs) or reactions (SARs) from randomisation to day 28 in the COVID STEROID 2 trial



Procedure for reporting serious adverse events and serious adverse reactions from randomisation to day 28 in the COVID STEROID 2 trial

List of SAEs that do not have to be reported to the sponsor within 24 hours of occurrence

SAEs seen frequently in critically ill patients with COVID-19 and/or critically ill patients in general are listed in the table below. The listed SAEs do not have to be reported to the sponsor within 24 hours of occurrence if adjudicated not to be related to the intervention and expected in the patent population.

Organ system	**Serious adverse events**
Nervous system	Stroke (1) Psychosis (2) Delirium (3) Seizures (2) Coma (2)
Respiratory system	Pneumothorax (4) Pneumonia (5) Acute respiratory failure (4)
Circulatory system	Severe heart failure, including cardiogenic shock (6) Cardiac arrest (6) Acute coronary syndrome (6) Sepsis (5, 7) Pulmonary embolus (8)
Digestive system	Pancreatitis (9) Acute hepatic injury (10) Ileus (11) Bowel ischemia (11)
Urinary system	Acute kidney injury (4, 12) Urinary tract infection (5)
Skeletal and muscular system	Soft tissue infection (5) Osteomyelitis (5)
Skin and soft tissue	Decubitus (13)
Endocrine system	Diabetic ketoacidosis and/or coma (14)
Blood and lymphatic system	Clinically important thrombosis (8) Clinically important bleeding* (15)

*Associated with transfusion of at least 2 units of red blood cells. If bleeding from the gastrointestinal tract, report as serious adverse reaction in the eCRF within 24 hours of occurrence.

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