

Hydrocortisone and Fludrocortisone for Critical Illness-related Corticosteroid Insufficiency

NCT04404400

Status	RECRUITING
Phase	Phase 3
Sponsor	Assistance Publique - Hôpitaux de Paris
Enrollment	1,092 participants

Key Eligibility Criteria

Inclusion (5)

- Adult (≥ 18 years);
- Hospitalized in an intensive care unit;
- SOFA score ≥ 4, for at least 6 consecutive hours;
- Informed written consent from patient or from legally authorized next of kin, or emergency deferred consent;
- Affiliation to a social security system or to a universal health coverage (Couverture Maladie Universelle, CMU).

Exclusion (17)

- Any suspected or proven acute adrenal insufficiency (As defined in international guidelines; basal cortisol < 5 µg/dL or peak (60) cortisol < 18 µg/dL)
- Expected death or withdrawal of life-sustaining treatments within 48 hours
- Known chronic adrenal insufficiency
- Concomitant treatment that inhibits cortisol production
- Septic shock (Singer Jama 2016)
- ... and 12 more (see full listing online)

Locations (1 total)

General Intensive care Unit, Raymond Poincaré Hospital, APHP, Garches, France