

MICU
STUDY

Ventricute

(rSP-C Surfactant)

Duration of Study:

The study will be conducted from January '04 until December 31st, 2005. LSUHSC expects to enroll approximately 3-4 patients per year.

Study Population:

Patients with pneumonia or aspiration of gastric contents.

Patients must be intubated and mechanically ventilated for 18-48 hours (h) and must, predominantly as a consequence of their pneumonia or aspiration, have a P/F ratio of ≤ 150 torr to enter baseline and of ≤ 170 torr to be randomized and treated.

Objective:

Instill Venticute via ETT to demonstrate increase in survival of patients with pneumonia or aspiration of gastric contents.

Study Groups:

Control: Group 1, standard care for patients with pneumonia or aspiration who suffer from acute lung failure: Patients will receive an initial application of Venticute and up to seven additional applications within 96 h from T₀ (first application). However, due to the use of blinding devices which will absorb the study drug, no study drug will reach the patients' lung.

T_x group: Group 2, standard care for patients with pneumonia or aspiration who suffer from severe acute lung failure plus Venticute: Patients will receive an initial application of Venticute and up to seven additional applications within 96 h from T₀ (first application). The blinding devices will allow the drug to reach the patient's lung.

Study Drug Administration:

Patients receive Venticute by intratracheal instillation after adequate sedation or neuromuscular blockade. Patients are alternately positioned in the left or right lateral decubitus position. The total volume of drug is given in two aliquots via an intratracheal catheter.

Treatment Overview:

Patients in both groups will receive initial treatment at T₀.

Time points for retreatment are 6, 12, 24, 36, 48, 72, and 96 hours after the initial application, if retreatment criteria are fulfilled at each time point.

Time Table: (see attached handout)

OUR ROLE...

After Study Approval:

Begin ARDSnet Ventilation Protocol (pamphlet provided on enrollment)

Perform vent check

Perform ABG – do not key into LIS (keep printouts in vent drawer)

Calculate P/F ratio (P_{aO_2}/F_{iO_2})

($>=60$ torr and ≤ 150 torr on PEEP of 5cmH₂O)

Perform EKG (do not transmit – print directory of patient)

2 hours from baseline vent ✓ / ABG

Perform vent check

Perform ABG – keep printouts in vent drawer (do not key into LIS)

Calculate P/F ratio

Randomization if: $60 \text{ torr} \leq P_{aO_2}/F_{iO_2} \leq 170 \text{ torr}$, PEEP ≥ 5 , Mean BP ≥ 60 torr

Treatment Period:

Dose patient

Perform 12 Lead ONLY if pt experiences rhythm disturbance after drug administration

Vent checks (Q2)

ABG (Q2)

6, 12, 24, 36, 48, 72, 96h after first dose:

Redose if: $P/F \geq 60$ & ≤ 170 , $PEEP \geq 5$

Day 6, day 7, day 14, day 21, day 28 (as long as pt is on mechanical ventilator):

Perform ABG

Perform vent checks (return to Q4 after day 5 or 4 hrs after final dose)

Day 28

Perform 12 Lead EKG