Does the Use of Prednisolone for Respiratory Insufficiency in Infants 34weeks Postmenstrual Age or Older Reduce the Need for Respiratory Support?

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BACKGROUND

The use of steroids in the Neonatal Intensive Care Unit is common. Hydrocortisone, dexamethasone, and prednisolone are among the most commonly prescribed medications in the Neonatal Intensive Care Unit.

The focus of research has been on antenatal steroids for the acceleration of fetal lung development prior to delivery, the treatment of congenital adrenal hyperplasia (CAH) and prevention or treatment of bronchopulmonary disease (BPD).

There is limited published data on the use of steroids for the treatment of respiratory insufficiency in newborns.
-Respiratory insufficiency is the symptomology of a condition in which the lungs cannot take in sufficient oxygen or expel sufficient carbon dioxide to maintain the physiologic needs for cellular function.

Prednisolone is a glucocorticoid that functions to upregulate surfactant synthesis, promote antioxidant enzymes, and inhibit inflammatory cell proliferation and infiltration reducing pulmonary edema.

While regularly prescribed there are well described side effects of the medication.

The use of Prednisolone in the neonatal population has become increasingly prescribed for the treatment of respiratory conditions, with limited data on the effectiveness of the intervention.

PURPOSE

To evaluate the efficacy of a five-day course of Prednisolone in reducing current reparatory support in infants 34 weeks postmenstrual age or greater.

METHODS

Study designs: randomized 1:1, double blinded, placebo-controlled trial at a single center.

Intervention: Prednisolone 1 mg/kg/day in 2 divided doses or placebo administered for five days.

Inclusion Criteria: Infants ≥ 34 weeks, not requiring invasive or non-invasive mechanical ventilation, requiring respiratory support of at least 0.1 liters per minute and unable to decrease level of support for 5 days.

Exclusion Criteria: Diagnosis of severe bronchopulmonary dysplasia (or patient would qualify if age criteria met), steroid administration within the last 7 days, need for steroid administration for any other indication, currently on diuretic therapy, previous enrolment in another clinical trial, and any condition that would make the participant unsuitable for the study, in the opinion of the investigator.

Primary outcomes:

- Decrease in support by 2lpm or greater
- Wean off respiratory support to room air
- Decrease in FiO2 by 20% or greater

Secondary outcomes:

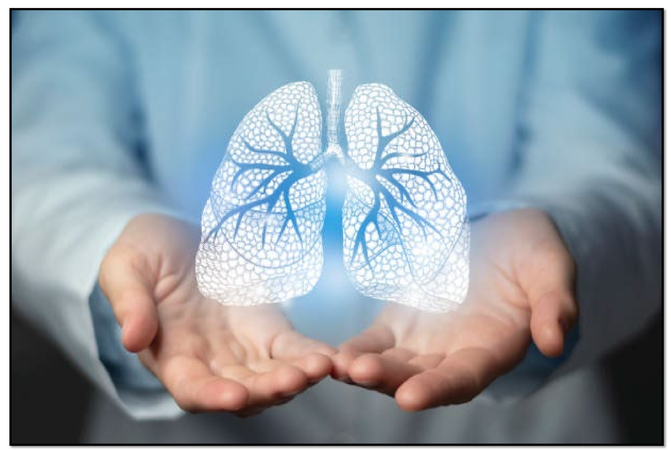
- Need to reinitiate respiratory support within 10 days post study period
- Need to increase support 1lpm or greater
- Blood glucose monitoring during study period (0-5 days)

Statistical analysis: Chi-Squared or Fisher's exact test as appropriate

RESEARCH/CONCLUSION

Limited research has been published outside of evaluating the effects of Prednisolone on the infant populations for prevention or treatment of BPD.

Research outcomes of this study for future dissemination



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(Pending IRB submission)