



# Development of an Optimal Corticosteroid Dosage Regimen for the Management of Acute Respiratory Distress Syndrome: A Sequential Explanatory Mixed Method Approach

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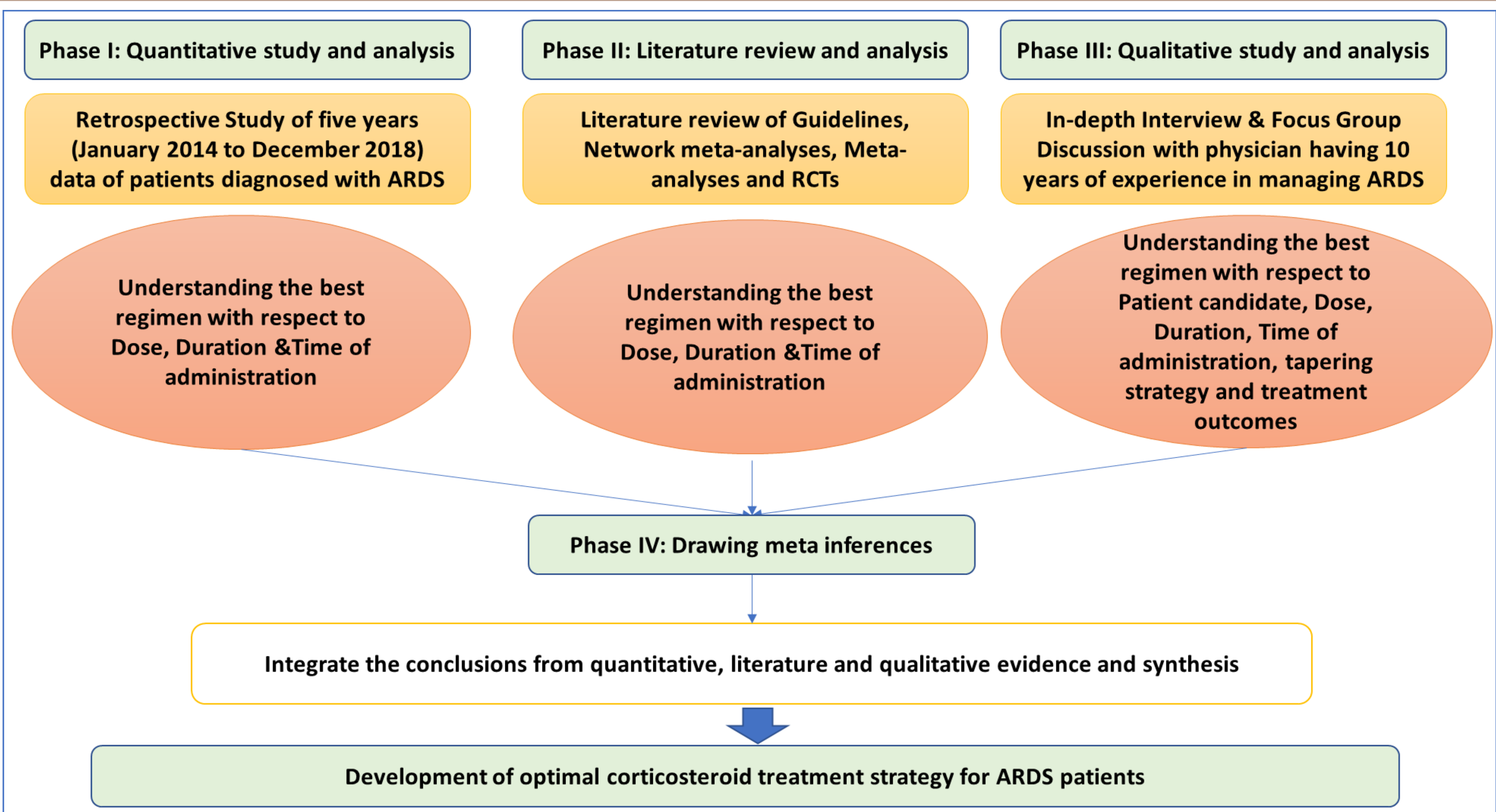
## Background

- There is no approved drug for the treatment of acute respiratory distress syndrome (ARDS) and still controversy exists among the treating physician
- The effectiveness of corticosteroids in the management of ARDS is still debatable, even in this era of modern medicine
- Disparities exist within both clinical practice and the body of literature regarding the use of corticosteroids in ARDS

## Objective

- This study aimed to develop an optimal corticosteroid treatment regimen for ARDS by drawing an inference from mixed method findings

## Methodology



## Results

Study Phase	Major Findings
Phase I	- Better recovery (p=0.002) , More Hospitalization, ICU, Ventilatory and oxygenation free days with low-dose for longer duration strategy - Better recovery at early administration (between 24-48 hours & 48-72 hours)
Phase II	- Effective in reducing mortality, Improving ventilatory, ICU and physiological outcomes - Low dose steroid ( 1 to 2 mg/kg) for prolonged administration (minimum of 7 days to 28 days) a early phase (24-72 hours) is better
Phase III	- Mixed opinion on use of steroid based on the clinical experience - Low dose (1-2 mg/kg) for longer duration (>7 days) High dose (>2 mg/kg) for shorter duration (<5 days) is comparatively better - Corticosteroid is cost effective and cheaper, Safe and no harm even in special population - Lack of good quality comparative RCTs

**Patients can be considered:** ARDS from atypical or organizing pneumonia; ARDS from viral diseases; Pneumonia with moderate to severe ARDS; Acute febrile illness-ARDS; Patients who are not responding to any other therapy, but steroid; Culture negative bacterial pneumonia with ARDS

**Patients can not be considered:** Secondary ARDS due to non-pulmonary pathology; Mild ARDS; Late onset ARDS (after 14 days of onset of symptoms); Burns with ARDS; Post surgical/operated patients; Immunocompromised/HIV infection; Fungal infections; Disseminated TB; Risk of GI bleeding; Other contraindications

## Phase IV: Proposed Corticosteroid Strategy

**Low dose** (1-2 mg/kg of methyl prednisolone or equivalent dose) for 3-5 days, tapering 50% of dose over 10 days **administered within 24-72 hours** of hospital admission or ARDS diagnosis (Ex: 80mg Methyl prednisolone as 40mg BD for 3-5 days, followed by 40 mg OD for 5 days, then gradual tapering) for a **total duration of >10 days** among **moderate to severe** ARDS patients

## Conclusion

This qualitative research suggests that **longer duration of low-dose steroid use in the early stages** of acute respiratory distress syndrome is comparatively safer and showed better clinical outcomes than other strategies

## References

- Annane D et al., *Critical care medicine*. 2006;34(1):22-30
- Rashid M et al., *Clinical Epidemiology and Global Health*, 2021; 13:100972.
- Meduri GU et al., *Chest*. 2007;131(4):954-63
- Ramakrishnan M et al., *Clin Epidemiol Glob Health* , 2023, 101243.
- Rietmeijer CBT et al. *Teach Learn Med*, 2022, 34(1), 113-121.
- Rashid M et al., *Int J Clin Pract*, 2021, 75(11):e14645.

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