

# A RANDOMISED FEASIBILITY TRIAL AND IN-VITRO PERFORMANCE OF A NEW SYSTEM FOR RESPIRATORY SUPPORT DURING INITIAL STABILISATION OF PRETERM INFANTS

Snorri Donaldsson<sup>1</sup>, Thomas Drevhammar<sup>2</sup>, Leena Taittonen<sup>3</sup>, Stina Klemming<sup>1</sup>, Baldvin Jonsson<sup>1</sup>

**Interface could be prongs or face-mask and usage is similar to T-piece**

**New system has low imposed work of breathing**

**A three armed randomised pilot revealed no problems with usage**



## Materials and Methods

Imposed work of breathing was determined in a mechanical lung model (sinusoidal flow, I:E 1:1, 16 ml TV and RR 60). The New System and the T-piece resuscitators were tested at increasing levels of CPAP at a fresh gas flow 10 l/min.

The feasibility trial included 36 infants (27-34 weeks gestational age). Exclusion criteria included: no need for respiratory support and known malformations. After consent the subjects were randomised into three groups: 1) T-piece (Neopuff) 2) New System - facemask or 3) New System - prongs. Randomisation was performed with sealed envelopes and 12 patients in each group. The patients were treated with CPAP 4 cm for a minimum duration of 10 min. Collected variables included problems with usage and safety. The response to respiratory support included time to stable breathing, need for PPV and intubation. The study had local ethics committee approval.

## Introduction

Resuscitation of newborn infants with prongs and CPAP with low imposed work of breathing could offer advantages to a standard T-piece resuscitator. We have developed a new resuscitation system that can be used with either prongs or face mask. The system is handled in a similar way to a T-piece resuscitator with positive pressure ventilation (PPV) provided by occlusion. CPAP is provided during PPV or spontaneous breathing. The aim of the study was: 1) to describe the in-vitro performance of the new system and 2) to perform a randomised feasibility trial for initial stabilisation of preterm infants.

## Impression

The clinical impression suggested that there was an advantage of the New System with prongs. The use of prongs as interface for resuscitation have previously been investigated by Capasso et al. 2005 and Lamberska et al. (poster at PAS 2014). There have been no trials of resuscitation using systems with low imposed work of breathing (iWOB)

## Hypothesis

Reduced iWOB and prongs could reduce delivery room (DR) intubation rates. DR intubation rates in Sweden were 50% in infants <28 weeks GA.

<sup>1</sup> Neonatology Department., Karolinska Hospital, Stockholm, Sweden

<sup>2</sup> Anesthesiology and ICU Department., Östersund Hospital, Östersund, Sweden

<sup>3</sup> Dept. of Paediatrics, Vaasa Central Hospital, Vaasa, Finland

Correspondance: [snorri.donaldsson@ki.se](mailto:snorri.donaldsson@ki.se)

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**Karolinska  
Institutet**