

IS A WOOLEN CAP EFFECTIVE IN MAINTAINING NORMOTHERMIA IN PRETERM INFANTS DURING KANGAROO CARE?

Interim analys results

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Background

Neonatal hypothermia is an important challenge associated with morbidity and mortality. Preventing neonatal hypothermia is important in high-resource countries, but is of fundamental importance in low-resource settings where supportive care is limited.

Kangaroo mother care (KMC) is a low-cost intervention that, whenever possible, is strongly recommended for temperature maintenance. During KMC, the World Health Organization (WHO) guidelines recommend the use of a cap/hat, but its effect on temperature control during KMC remains to be established.

Aim

In this poster, we present the results of the interim analysis, planned after the enrollment of 100 patients, of a larger RCT aimed to assess the effectiveness and safety of using a woolen cap in maintaining normothermia in low-birth-weight infants (LBWI) during KMC.

Methods

SETTING: Three hospitals in three African countries (Mozambique, Ethiopia and Uganda) where Doctors with Africa CUAMM has ongoing projects on maternal-neonatal health. Axillary temperature was measured 4 times per day. Maternal and room temperature were also recorded.

The protocol was approved by the local Ethics Committees for human investigation.



Central Hospital of Beira Mozambique , Level III



St. Luke Wolisso Hospital, Ethiopia, Level II



Aber Hospital, Uganda, Level I

Design

Multi-center, prospective, unblinded, randomized clinical trial of KMC treatment with and without a wool cap in LBWI.

Inclusion criteria

1. Birth weight below 2500 g (and);
2. Candidate to KMC treatment (and);
3. Parental consent.

Exclusion criteria

1. Major congenital malformations;
2. Twins;
3. Parental refusal to participate in the study.

Primary Outcome

Time spent in the normal temperature range (36.5-37.5°C) during KMC.

Secondary Outcomes

1. Episodes of apnea;
2. Sepsis;
3. Mortality;
4. In-hospital growth;
5. Age at discharge.

Results

The first 100 subjects (70, 23, and 7 at Beira, Wolisso and Aber hospital, respectively) were enrolled between December 2015 and February 2016. Main results are shown in table 1.

Table 1

	CAP arm (n.49)	No-CAP arm (n. 51)	p-value
Time in range (36.5°C-37.5°C), median (IQR), %	50 (38-64)	56 (52-70)	0.52
Death, n (%)	2 (4.0)	3 (5.8)	0.99
Severe hyperthermia (temperature >39 °C), n (%)	2 (4.0)	0 (0)	0.24
Severe hypothermia (temperature <35 °C), n (%)	3 (6.1)	5 (9.8)	0.71

Conclusion

According to study protocol, there were no reasons for stopping for harm.

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