Prevention of hypothermia in preterm infants with a plastic head cap.

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Study the effect of a plastic cap during the resuscitation of a preterm infant on heat loss and temperature at admission to the NICU.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35490

Source ToetsingOnline

Brief title Prevention of hypothermia with a plastic cap.

Condition

• Other condition

Synonym heat loss, hypothermia

Health condition

temperatuur controle bij prematuur

Research involving Human

Sponsors and support

Primary sponsor: Isala Klinieken Source(s) of monetary or material Support: niet van toepassing. plastic muts wordt zelf

gemaakt;onderzoek in kader vna een afstudeerproject voor verpleegkundig specialist. Hieraan zijn geen kosten verbonden.

Intervention

Keyword: hypothermia, plastic cap, preterm

Outcome measures

Primary outcome

Does the use of a plastic cap in preterm infants born by caeserean section

reduces heat loss, measured after admission to the NICU

Secondary outcome

remains this effect during the first 2 hours after admission to the NICU.

Study description

Background summary

An important item in the care of preterm infants is the maintenance of a neutral body temperature. The smaller and more immature the infant is, the higher the risk of heat loss. Hypothermia in the preterm infant increase the risk of respiratory and cardiovascular instability. The risk of heat loss is the greatest at birth, especially when the infant is born in a cold environment as the operating room. Despite the measurements taken to prevent heat loss such as wrapping the body in plastic substantial heat loss still occurs.

We speculate that covering the heat in plastic could prevent heat loss. In preterm infant the head is large compared to the body and is it known that this results in substantial heat loss, which can only be partly prevented by the normal cap now used.

Study objective

Study the effect of a plastic cap during the resuscitation of a preterm infant on heat loss and temperature at admission to the NICU.

Study design

Randomised controlled trial. Blinding is not possible due to the visible aspect of the cap.

If a pregnant woman is admitted to the obstretic ward the attending neonatologist or the investigator will ask permission for the study to the future parents.

Before every birth of an infant < 32 weeks with a caeserean section infants will be stratified and randomised to be treated with a plastic cap or the usual tricot cap. Immediately afer birth the cap will be put on the head of the infant and will remain there during the first 2 hours after admission on the NICU. The control group with the tricot cap will get a clean and dry cap when they are admitted to the unit. This cap will remain during the first 2 hours after admission. Body temperature will by measured rectally immediately after admission on the NICU and 1 and 2 hours later skin measurements will be taken. The plastic cap will be manufactured by the investigator since these caps are not commercially available.

Intervention

all infants will be rsuscitated according to the excisting protocol. This means that they will be put on a Panda®Warmer and put immediately in a plastic bag without previous drying. All infants get a cap immediately after birth. When used a tricot standard cap (control group) the head will be dried before the cap is put on the head. When a plastic cap is used (study group) the head is not dried and the cap is put on immediately. After stabilisation of the infant, the infant is transported to the NICU in a transport incubator and admitted to the unit in an incubator and treated according to the unit policy.

Standard cap

in the Isala clinics tricot caps are used (infant caps, Medline Industies, Inc.). After admission to the unit this cap will be replaced by a dry cap.

Plastic cap

these cap will be made by the investigator since these caps are not commercially available. There has been contact with a previous investigator on this topic (D.Trevisanuto), she also used hand made caps.

Study burden and risks

Not applicable

Temperature measurements are standard procedure for all preterm infants. We expect that the texture of the cap (plastic instead of tricot) wil not substantially disturbe the infant.

Contacts

Public Isala Klinieken

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Children (2-11 years)

Inclusion criteria

preterm infants < 32 weeks born by caesarean section in the Isala clinics Zwolle admitted to the NICU Isala clinics Zwolle

Exclusion criteria

severe congenital malformations severe skin defects

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-11-2011
Enrollment:	100
Туре:	Anticipated

Medical products/devices used

Generic name:	plastic cap
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO	
Date:	17-11-2011
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register

ССМО

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