Title Form

"Delayed umbilical cord clamping in elective Caesarean Section: What are the benefits?"

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Study Protocol

Principal Investigator

Dr. Giuseppe De Bernardo, responsible S. S. Neonatal Intensive Care Unit

Department of mother and child's Health

Poliambulanza Foundation, Brescia

Co - principal investigator

Dr.ssa Laura Linetti

Neonatology Coordinator

Poliambulanza Foundation, Brescia

Statistic

Maurizio Giordano

University of Naples Federico II, School of Medicine

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1. Introduction

Umbilical cord cutting determines the separation of the newborn from mother. Umbilical cord clumping consists in the binding of the umbilical cord by nipper to interrupt blood flow from placenta to foetus (1). In the spontaneous labor there are two modalities to obtain umbilical cord clamping: the first modality is immediate umbilical cord clamping within 30s from birth. The second modality is delayed umbilical cord clamping at least 1 min after birth. After 1 min, cerebral blood flow is reduced again because of lower cardiac output (2-3).

A lot of studies have shown that delayed umbilical cord clamping is better than the early umbilical clamping because delayed umbilical cord clamping is associated with a great haemoglobin concentration in the newborns and best iron storage between 3-6 months of life and less incidence for transfusion and neonatal hypotension (4-5-6-7). Experimental studies, executed on animals and humans, analysed cardiocirculatory changes in the foetus immediately after birth and the importance of the delayed clamping for the hemodynamic stabilization, particularly in the lowest gestational age (8-9).

In a recent randomized study conducted in Nepal on 540 newborns, birth by eutocic delivery with 39.2 weeks of gestational age, showed that delayed umbilical cord clamping after 3 min of life is correlated with a better haemoglobin level and less incidence of anaemia at 8 months of life (10). Zhou et al. conducted a meta-analysis that included hematologic parameters obtained by umbilical cord, placenta and newborns blood.

Association of Italian Hospital Gynecologists Obstetricians (AOGOI) declared contraindicated conditions to execute a delayed umbilical cord clamping:

Hypoxic-ischemic events: detachment of placenta, prolapse of the funiculus, uterine rupture, shoulder dystocia, premature rupture of fetal membranes, placenta previa, maternal collapse, embolism amniotic, maternal cardiac arrest. Monochorionic twins, Fetal Hydrops, Umbilical cord damaged, Isoimmunization Rh.

Researchers concluded that newborns subjected to Caesarean Section showed greater value of haemoglobin and lower value of red blood cells compared to newborns birth by vaginal delivery. Haematocrit difference was greater between newborns birth by elective Caesarean Section compared to those birth by Caesarean Section in labor (11). Nowadays, researchers found no side effects of delayed umbilical cord clamping except a slight increase of phototherapy needs (12).

Despite evidence of beneficial effects for delayed umbilical cord clamping after eutocic delivery, this practice is not yet taken into consideration after elective Caesarean Section. The aim of the study protocol is to investigate the effects of the clamping after 1 min from birth by elective Caesarean Section on heart rate, saturation, body temperature, bilirubin, haematocrit and glycemia.

2. Objective

Objective of the study was evaluating the effect of delayed clamping on FC, SpO2, T, HGT, Ht and bilirubin in term newborns subjected to elective Caesarean Section

3. Study Location

- U.O.C. NICU-Neonatology – Department of mother and child's Health
Poliambulanza Foundation, Brescia
- U.O. Gynecology ed Obstetrics - Villa Cinzia Clinic, struttura accreditata, Napoli

4. Population

46 term newborns (37-42 wks) subjected to Caesarean Section will be enrolled:

1. Group (A): 23 newborns subjected to umbilical cord immediate clamping

2. Group (B): 23 newborns subjected to umbilical cord delayed clamping

5. Inclusion Criteria

5.1 Mothers:

· Caesarean Section;

· BMI = 19-24,9;

· Age ≤ 37 years

5.2 Newborns

· Gestational Age: 37 e 42 wks

· Birth Body Weight = Appropriate gestational age

6. Exclusion Criteria

6.1 Mothers

· Pathologies;

· Smoking mothers;

· Assumption of drugs during pregnancy

· Mother toxicomaniac

6.2 Newborn

· Admission in NICU;

- Neonatal Resuscitation

· Hypoxic-ischemic events: detachment of placenta, prolapse of the funiculus, uterine rupture, shoulder dystocia, premature rupture of foetal membranes, placenta previa, maternal collapse, embolism amniotic, maternal cardiac arrest

- Monochorionic twins

· Fetal Hydrops

· Umbilical cord damaged

· Isoimmunization Rh

· Respiratory and malformative diseases;

· Small for gestational age

· Large for gestational age

· Temperature <36,5 C

· Temperature > 37,5 C

· Acidosis

7. Procedure and Measurement

· Immediate umbilical cord clamping in the Group A

· Delayed umbilical cord clamping after 1 min from birth in Group B

In both groups will be evaluated:

- **Saturation:**

Saturation will be detected at 5 min and 10 min from birth by oximeter Covidien, positioning the probe on right hand/wrist of the newborn. References value are: 80-85% at 5 min and 85-90% at 10 min (14);

- **Heart Rate:**

Heart rate will be detected at 5 min and 10 min from birth by cardiomonitor. Reference value are 100-150 bpm (15)

- **Temperature:** Temperature will be revealed at 5 min and 10 min from birth by Panda Warmer (GE), the probe of the infant radiant warmer. Reference value are 36,5-37,5 C
- **Glycaemia:** HGT will be detected at 120 min from birth by capillary blood sampling of the heel. The sample will be analysed by "ABL90 Flex"
- **Haematocrit:** Ht will be revealed at 120 min and 72 hrs from birth by capillary blood sampling of the heel. The sample will be analysed by "ABL90 Flex"
- **Bilirubin:** Bilirubin will be detected after 72 hrs from birth by capillary blood sampling of the heel. The sample will be analysed by "ABL90 Flex"

8. Primary Outcome

H0: The case group will show the same values respect to control group for HR, SpO_2 and Temperature

H1: The case group will show different values respect to control group for HR, SpO_2 e Temperature

9. Secondary Outcome

H0: The case group will show the same values respect to control group for HGT, bilirubin and Ht

H1: The case group will show different values respect to control group for HGT, bilirubin and Ht

10. Sample Size

Primary outcome will be analysed by ANOVA, repeated measures, between-within. Setting:

· **alfa error:** 5%

· **beta error:** 10%

· **Number of groups:** 2

· **Number of measurements: 2**

· **Correlation of repeated measures:** 0,5

· **Nonsphericity correlation:** 1

· **Effect size:** 0,25

They will be enrolled 46 newborns (23 group A + 23 group B)

Secondary outcome will be analysed by ANOVA test. Statistical analysis will be performed by IBM SPSS Statistics for Windows, version 25.0 (Armonk, NY: IBM Corp.)

11. Randomization

Non-commercial study, case-control, randomized, open. Patients will be assigned to Group A or Group B by statistical software.

12. Reference

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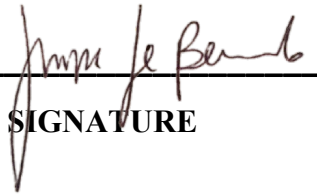	15-10-2018
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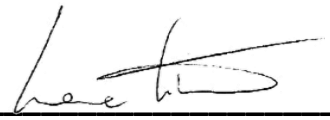	15-10-2018
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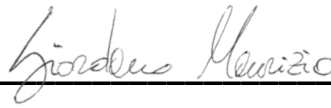	15-10-2018
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