Azienda Ospedaliero Universitaria Careggi

SOD Neonatologia e Terapia Intensiva Neonatale

DAI Materno-Infantile

AOU Careggi

Mod. C2.a
Vers_20160118

INFORMATION SHEET
FOR PARENTS/LEGAL GUARDIAN

Study title: Study protocol: treatment with caffeine of the very preterm infant in the delivery room: a feasibility study

Protocol code, version, and date: CAFSP01, version 1.0, 01/04/2018
Study promotor: Careggi University Hospital of Florence

Principal Investigator: Prof Carlo Dani, Division of Neonatology Careggi University Hospital of Florence.

Dear Parents / Guardian,
We ask you to accept participation to this study only after having carefully read this information sheet and having had a thorough interview with the investigating physician who will have to dedicate the time necessary to fully understand what is proposed.

Why we do this study

Caffeine is a drug that is administered to all very preterm infants from the first hours of life to prevent the onset of apneas, caused by the immaturity of the breathing center, in order to reduce the risk of endotracheal intubation and mechanical ventilation. This study aims to evaluate in a small group of newborns whether the early administration of enteral or intravenous caffeine is already possible in the delivery room in the first minutes after birth. If the study will be successful, it will be possible to plan a further larger study to see if administering caffeine so early is beneficial in reducing the risk of mechanical ventilation in comparison with the current later use.

What are the characteristics of this study and what participation in the study entails

Newborns of gestational age of 25^{+0}-28^{+6} weeks who are at high risk of developing respiratory distress syndrome and who did not require mechanical ventilation in the delivery room will be eligible in the study.

In case you decide that your daughter / son can participate in the study, after signing the consent form, she/he you will receive a dose of caffeine within 10 minutes of birth enterally, through a

Dani C, *et al. BMJ Open* 2020; 10:e040105. doi: 10.1136/bmjopen-2020-040105

nasogastric tube, or intravenously through the umbilical vein. The choice of the route of administration of the drug will take place in a randomized manner, ie random. Subsequently, and only in cases in which the administration has been successful, the dosage of the concentration of caffeine in the blood will be carried out approximately one hour after the administration and one hour before the next dose, to objectively confirm that the administration has taken place. effectively. The dosage will be performed on small amounts of blood taken from the puncture of the newborn's heel and collected on a special card during other samples that would still be performed for the monitoring of these very preterm newborns. The dosage will be performed at the Laboratory of Chemistry and Clinical Pharmacology of the A. Meyer Pediatric Hospital in Florence. The samples will be anonymized and will be kept for 7 years in the same laboratory.

Benefits and risks of participating in the study

Although an immediate direct benefit from participation in the study cannot be demonstrated, if the next larger study will demonstrate that caffeine administered in the delivery room is effective in preventing mechanical ventilation, it can be inferred that the infants treated in this preliminary study have had the advantage of a lower risk of endotracheal intubation and mechanical ventilation. The conclusions of this study and the subsequent study could therefore contribute to improving the care of preterm infants.

Caffeine is a drug used in all very preterm infants and it is considered so safe that in clinical practice it is not recommended for its blood dosage to be sure that the safe therapeutic concentration is not exceeded. Possible side effects reported in the newborn are tachycardia (which disappears when the drug is discontinued) and seizures in case of overdose. However, since tachycardia always precedes seizures, the withdrawal of caffeine that follows the onset of tachycardia effectively prevents the potential for seizures. Therefore, participation in this study, since it encompasses administering caffeine a few hours (1-4) earlier thatn it would anyway, will not include additional risks compared to common clinical practice.

What happens if you decide not to take part in the study or to withdraw from the study

Participation in the study is entirely voluntary. If you decide not to take part in the study, your daughter / son will not suffer any penalty or loss of future benefits to which he would otherwise be entitled at the Careggi University Hospital.

Azienda Ospedaliero Universitaria Careggi

SOD Neonatologia e Terapia Intensiva Neonatale

DAI Materno-Infantile

AOU Careggi

INFORMATION REGARDING THE PROCESSING OF PERSONAL DATA

Data controllers and related purposes

The Neonatal Intensive Care Unit of Careggi University Hospital which proposed the study that has been described to you, for the areas of its competence and in accordance with the responsibilities provided for by the rules of good practice, will process personal data of your child, in particular those on health and, only to the extent that are indispensable in relation to the objective of the study, exclusively in relation to the implementation of the study.

The processing of personal data of your child is essential for the study: refusal to provide them will not allow to participate in the study.

Nature of the data

The physician who will follow you in the study will identify you with a code: data concerning your daughter/son collected during the study will be recorded, processed and stored for at least 7 (seven) years from the conclusion of the study. Only the physician and authorized persons can link this code to your child.

Processing methods

The data, also processed by means of electronic means, will be disclosed only in a strictly anonymous form, for example through scientific publications, statistics and scientific conferences.

Exercise of rights

You can exercise the rights listed in art. 7 of the Privacy Code (eg. Access the data of his / her son / daughter, integrate them, update them, rectify them, oppose their treatment for legitimate reasons, etc.) by contacting the trial center directly and in particular Prof. Carlo Dani, Neonatal Intensive Care Unit of Careggi University Hospital, telephone 055 7948421.

Azienda Ospedaliero Universitaria Careggi

SOD Neonatologia e Terapia Intensiva Neonatale

DAI Materno-Infantile

AOU Careggi

Further information

There are no additional costs for you resulting from participation in the study. You will not receive any financial compensation for participating in the study. The protocol of the study proposed to you was drawn up in accordance with the Standards of Good Clinical Practice and the Declaration of Helsinki, and was approved by the Ethics Committee of the Tuscany Region, Pediatric Section, on April 15, 2019.

For further information and communications during the study, the following staff will be available: prof. Carlo Dani, phone 055 7918421, email cdani@unifi.it

_____ ___/___/_____ _____

Name of physician who gives Information sheet | Date | Hour

Modulo informativo e consenso per genitori/tutore legale
Versione: 1.0 del 01/04/2018
Studio: **TRATTAMENTO DEL NEONATO MOLTO PRETERMINE CON CAFFEINA IN SALA PARTO: STUDIO DI FATTIBILITA'**

Azienda Ospedaliero Universitaria Careggi

SOD Neonatologia e Terapia Intensiva Neonatale

DAI Materno-Infantile

AOU Careggi

Mod. C2.b
Vers_20160118

INFORMED CONSENT FOR PARENTS/LEGAL GUARDIAN

Study title: Study protocol: treatment with caffeine of the very preterm infant in the delivery room: a feasibility study

Protocol code, version, and date: CAFSP01, version 1.0, 01/04/2018
Study promotor: Careggi University Hospital of Florence

Principal Investigator: Prof Carlo Dani, Division of Neonatology Careggi University Hospital of Florence.

I, the undersigned (mother/legal guardian)
_____ born on ___/___/_____resident in _____ address _____
phone_____

I, the undersigned (father/legal guardian)
_____ born on ___/___/_____resident in _____ address _____
phone_____

Of the minor _____ born on ___/___/_____

I declare that I have received from Doctor _____ exhaustive explanations regarding the request to participate in the study, as reported in the information sheet, of which I was given a copy on _____ at _____ (indicate date and time of delivery).
I declare that the nature, purpose, procedures and benefits of the study have been clearly explained to me.

Azienda Ospedaliero Universitaria Careggi

SOD Neonatologia e Terapia Intensiva Neonatale

DAI Materno-Infantile

AOU Careggi

I also DECLARE that:

1. I have read and understood the information sheet provided regarding the research project and forming part of this consent;
2. I was given the opportunity to ask any question to the investigator of the study and I received satisfactory answers;
3. I was given sufficient time to reflect on the information received and to discuss it with third parties;
4. I was informed that the study protocol and all the modules used have had the favorable opinion of the competent Ethics Committee;
5. it was clearly explained to me that I can decide that the minor does not take part in the study and that such decisions will not modify in any way the relations with the treating doctors and with the facility where I am being treated;
6. I have been informed that the results of the study will be disclosed to the scientific community, protecting the identity of the minor in accordance with current privacy legislation.
7. I am aware that I must receive a copy of this informed consent.

Therefore I DECLARE TO:

☐ **WANT** ☐ **NON WANT**

that the minor participate in the study

_____	___/___/_____	_____
Name of minor	Date	hour

_____	___/___/_____	_____	_____
Name of mother/legal guardian	Date	hour	Signature

_____	___/___/_____	_____	_____
Name of father/legal guardian	Date	hour	Signature