miniNO-COVID - Exploratory multicenter observational study to assess the outcome of infants with perinatal SARS-COV-2 infection and its link with the NO pathway: the minipuberty hypothesis

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General

Identification

Detailed name	Exploratory multicenter observational study to assess the outcome of infants with perinatal SARS-COV-2 infection and its link with the NO pathway: the minipuberty hypothesis
Sign or acronym	miniNO-COVID
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	2020-A02122-37

General Aspects

Medical area	Biology Endocrinology and metabolism Neurology Pediatrics
Study in connection with Covid-19	Yes

Scientific investigator(s) (Contact)

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Surname	Laurent
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Unit	Neonatal Intensive Care Unit of the CHU of Lille; FHU 1000 days for health
Organization	CHU Lille

Name of the director	PREVOT
Surname	Vincent
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Unit	Laboratory of Development and Plasticity of the Neuroendocrine Brain; Lille Neuroscience & Cognition; FHU 1000 days for health
Organization	Inserm, Univ. Lille, CHU Lille

Collaborations

Participation in projects, networks and consortia	Yes
Details	European consortium

Funding

Funding status	Public
Details	European Union's Horizon 2020 research and innovation program under grant agreement No 847941 (miniNO)

Governance of the database

Sponsor(s) or organisation(s) responsible	CHU LIlle
Organisation status	Public
Presence of scientific or steering committees	Yes
Labelling and database evaluation	miniNO council members

Additional contact

Main features

Type of database

Type of database	Study databases

Study databases (details)	Case control study
Database recruitment is carried out by an intermediary	A selection of health care professionals
Database recruitment is carried out as part of an interventional study	No

Database objective

Main objective	To compare the follicle stimulating hormone (FSH) plasma concentrations measured at the postnatal age of 3 months between the three matched (on gestational age at birth, postnatal age and respiratory failure) newborn infants groups
Inclusion criteria	o Newborn infants (24 to 41 weeks gestational age) or young infants (< 3 months) admitted at the maternity ward or at the Department of Neonatology at Jeanne de Flandre Hospital, CHU of Lille with perinatal COVID-19 infection defined by: o Antenatal COVID-19 infection: pregnant women with positive PCR test at any time of the pregnancy; o Post-natal COVID-19 infection: newborn or young infants (< 3 months) with positive PCR test in pharynx or stools as part of their treatment. o Newborn infants (24 to 41 weeks gestational age) or young infants (< 3 months) admitted at the maternity ward or at the Department of Neonatology at Jeanne de Flandre Hospital, CHU of Lille for severe cardiorespiratory diseases requiring inhaled NO treatment. o The control group without perinatal COVID-19 infection will be matched to thevtreatment group on gestational age at birth (± 2 weeks of gestation), on postnatal age (± 3 weeks) and respiratory failure. o No inclusion in another ante- or post-natal trial; o Written consents from both parents;

Population type

Age	Newborns (birth to 28 days) Infant (28 days to 2 years)
Population covered	Sick population
Pathology	IV - Endocrine, nutritional and metabolic diseases
	V - Mental and behavioural disorders
	VI - Diseases of the nervous system

Gender	Male Woman
Geography area	International
Detail of the geography area	France, Germany, Switzerland, UK, Belgium and Greece

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	Fevrier 2021

Size of the database

Size of the database (number of individuals)	< 500 individuals

Data

Database activity	Current data collection
Type of data collected	Clinical data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	Clinical examination, body weight, size, vital signals; Clinical examination; Hearing evaluation Olfactive assessement; Brain-to-brain dyad synchrony; ASQ-3 and ASQ-SE assessment; Bayley scale - III
Biological data (detail)	FSH/LH plasma concentration; Hormonal test (blood sampling) - Estrogen (females) - Testosterone (males) - AMH (females) - PSA (males); Metabolite assessment (blood sampling) - Glucose, - Insulin, - Leptin, - Nitrates in urine sample; Genetic counseling (blood sampling for genetic and epigenetic screening)
Presence of a biobank	No

Procedures

Data collection method	Once the patient is included in the study, an investigator manually collects demographic data, as well as data related to the intervention. This collection is pseudonymized: only the first letter of the name and the first letter of the first name

	appear on the collection sheet.
Participant monitoring	Yes
Monitoring procedures	Monitoring by convocation of the participant
Details on monitoring of participants	At Corrected age of 9 month: - Clinical examination and cardiovascular assessment; - Blood sampling (2 ml) for the measurement of reproductive hormones and sampling for miRNA screening; - ASQ-3 and ASQ-SE-2 assessment by the parents; - Bayley ? III assessment; - Measure of the brain-to-brain synchrony in the mother-baby dyad in different social contexts (mutual-gaze vs non-interactive periods). We will also focus on social cognition, since this cognitive domain is regularly impaired in neurodevelopemental disorders (including autism). In this context, we will not only explore the child development and ability but consider the dyadic system gathering the child and her/his mother. We will assess mother-child interactions at 9 months of corrected age looking at brain-to-brain synchrony between these two partners. We will focus on two distinct periods: mutual gaze interactions versus non-interactive periods and refer to two ecological and non-invasive systems dedicated to these measures: 2x eye-tracking glasses and 2x high-density EEG systems (electroencephalography) for the child and her/his mother. At the age of 18 months: ASQ-3 and ASQ-SE-2 assessment by the parents
Followed pathology	V - Mental and behavioural disorders
	IV - Endocrine, nutritional and metabolic diseases
Links to administrative sources	No

Promotion and access

Promotion

Access

Dedicated website	https://www.minino-project.com
Access to aggregated data	Access not yet planned
Access to individual data	No access