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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Général

Identification

Nom détaillé	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
Sigle ou acronyme	miniNO-COVID
Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.)	2020-A02122-37

Thématiques générales

Domaine médical	Biology Endocrinology and metabolism Neurology Pediatrics
Etude en lien avec la Covid-19	Yes

Responsable(s) scientifique(s)

Nom du responsable	STORME
Prénom	Laurent
Adresse	Hôpital Jeanne de Flandre, CHU Lille Avenue Eugène Avinée, 59037 LILLE CEDEX
Laboratoire	Neonatal Intensive Care Unit of the CHU of Lille; FHU 1000 days for health
Organisme	CHU Lille
Nom du responsable	PREVOT
Prénom	Vincent

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Laboratoire	Laboratory of Development and Plasticity of the Neuroendocrine Brain; Lille Neuroscience & Cognition; FHU 1000 days for health
Organisme	Inserm, Univ. Lille, CHU Lille

Collaborations

Participation à des projets, des réseaux, des consortiums	Yes
Précisions	European consortium

Financements

Financements	Public
Précisions	European Union's Horizon 2020 research and innovation program under grant agreement No 847941 (miniNO)

Gouvernance de la base de données

Organisation(s) responsable(s) ou promoteur	CHU LIlle
Statut de l'organisation	Secteur Public
Existence de comités scientifique ou de pilotage	Yes
Labellisations et évaluations de la base de données	miniNO council members

Contact(s) supplémentaire(s)

Caractéristiques

Type de base de données

Type de base de données	Study databases
Base de données issues d'enquêtes, précisions	Case control study

Origine du recrutement des participants	A selection of health care professionals
Le recrutement dans la base de données s'effectue dans le cadre d'une étude interventionnelle	No

Objectif de la base de données

Objectif principal	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
Critères d'inclusion	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;

Type de population

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

Sexe	Male Woman
Champ géographique	International
Détail du champ géographique	France, Germany, Switzerland, UK, Belgium and Greece

Collecte

Dates

Année du premier recueil	Fevrier 2021

Taille de la base de données

Taille de la base de données (en nombre d'individus)	< 500 individuals

Données

Activité de la base	Current data collection
Type de données recueillies	Clinical data Biological data
Données cliniques, précisions	Direct physical measures Medical registration
Détail des données cliniques recueillies	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
Données biologiques, précisions	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)
Existence d'une biothèque	No

Modalités

Mode de recueil des données	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.

Suivi des participants	Yes
Modalités de suivi des participants	Monitoring by convocation of the participant
Détail du suivi	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
Pathologie suivies	V - Mental and behavioural disorders
	IV - Endocrine, nutritional and metabolic diseases
Appariement avec des sources administratives	No

Valorisation et accès

Valorisation et accès

Accès

Site internet dédié	https://www.minino-project.com
Accès aux données agrégées	Access not yet planned
Accès aux données individuelles	No access