EDIFICE - Observational study on the diagnostic evaluation of the intestinal microbiota of French people infected with the Coronavirus

Head: MARTI Guy

Collaborations

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| General | | | |
| Identification | | | |
| Detailed name | Observational study on the diagnostic evaluation of the intestinal microbiota of French people infected with the Coronavirus | | |
| Sign or acronym | EDIFICE | | |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | 20.04.14.68238 | | |
| General Aspects | | | |
| Medical area | Gastroenterology et hepatology Immunology Infectious diseases Internal medicine | | |
| Study in connection with Covid- 19 | Yes | | |
| Health determinants | Others (specify) | | |
| Others (details) | Microbiota | | |
| Keywords | intestinal microbiota | | |
| Scientific investigator(s) (Contact) | | | |
| Name of the director | MARTI | | |
| Surname | Guy | | |
| Email | guy.marti@doctocare.com | | |
| Organization | Clinique St Jean de l'Hermitage | | |

| Funding | |
|--|--|
| Governance of the database | |
| Sponsor(s) or organisation(s) responsible | LUXIA SCIENTIFIC |
| Organisation status | Private |
| Presence of scientific or steering committees | Yes |
| Additional contact | |
| Name of the contact | CERVINO |
| Surname | Alessandra |
| Address | HCenter, >11 Rue Benjamin Franklin >77000 La Rochette |
| Email | acervino@luxia-scientific.com |
| Organization | Luxia Scientific |
| Main features | |
| Type of database | |
| Type of database | Others |
| Specify | CRF |
| Database recruitment is carried out by an intermediary | A selection of health institutions and services |
| Database recruitment is carried out as part of an interventional study | No |
| Database objective | |
| Main objective | Validate the hypothesis for a relationship between the loss of diversity of the intestinal microbiota and screening positive for COVID-19, by comparing hospitalised COVID-19 positive patients with an exposed French population represented by hospital medical and paramedical personnel |
| Inclusion criteria | COVID-19 positive patients: hospitalised patients diagnosed with COVID-19 in one of the two investigating sites, and able to provide a stool |

| | Exposed subjects: Medical and paramedical personnel working at one of the two investigating sites, having been in direct contact with the patients. Aged between 18 and 85 years Subjects able to read the French-language study information leaflet Patients with social cover |
|--|--|
| Population type | |
| Age | Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more) |
| Population covered | General population |
| Pathology | |
| Gender | Male Woman |
| Geography area | National |
| Detail of the geography area | Ile de France and Loire Atlantique |
| Data collection | |
| Dates | |
| Size of the database | |
| Size of the database (number of individuals) | < 500 individuals |
| Details of the number of individuals | 160 |
| Data | |
| Type of data collected | Clinical data Biological data |
| Clinical data (detail) | Direct physical measures |
| Biological data (detail) | Analyses of the intestinal microbiota by 16s |
| Presence of a biobank | No |
| | |

Health parameters studied Health event/mortality

| Procedures | |
|---------------------------------|-----------|
| Data collection method | Paper CRF |
| Quality procedure(s) used | ISO13485 |
| Participant monitoring | No |
| Followed pathology | |
| Links to administrative sources | No |

Promotion and access

Promotion

Access