INSTITUT PASTEUR
25-28 Rue du Dr Roux, 75015 Paris, France

Information document for subjects in the cohort

"Elucidation of the pathogenesis of HTLV-1 related diseases"

Impact of cerebrospinal fluid from TSP/HAM patients on neural cells (HINC) « SinCeH ».

Dear Sir/Madam,

You have participated in the St. Marianna University Graduate School research program due to infection by HTLV-1 virus. During your participation, biological samples Cerebro-Spinal Fluid « CSF » and corresponding PBMCs (peripheral blood mononuclear cell) were taken and data concerning you were collected.

A new "SinCeH" study will be conducted by Institute Pasteur in collaboration with St. Marianna University Graduate School in Japan, a scientific cooperation dedicated to neurodegenerative illness. This collaboration will enrich our knowledge by investigating myelopathy « HAM » and tropical spastic paraparesis "TSP" disorders and will help to understand why some patients' disease progresses fast or slowly.

For this new study « SinCeH », we will reuse your samples already collected as part of the HAM/TSP pathogenesis cohort and compare them with samples from patients with similar illnesses: there will be no new sampling. If you are not infected, your samples will be only used as controls.

Study objectives

HAM/TSP results from the infiltration of HTLV-1[1] () infected lymphocytes into the central nervous system. At the site of infiltration, the secretome[2] of infected lymphocytes alters the functions of neural cells. We want to study the changes in nervous cells in response to the lymphocyte secretome. The disease is associated with changes in CSF composition, which has been used as a marker of the disease. We want to investigate the effect of CSF changes on nervous cells. Analyzing the response of nervous cells to CSF from uninfected donors, asymptomatic donors or people with HAM/TSP on nervous cells will help to better understand the mechanisms and progression of HAM/TSP.

This knowledge could, in the future, guide the development of alternative or complementary treatments to prevent or treat neurodegenerative diseases such as: tropical spastic paraparesis or myelopathy.

How the study works

Your CSF and PBMC samples, collected as part of the HAM/TSP cohort developed by Pr Yamano from St. Marianna University Graduate School in Japan and part of the RADDA-J biobank, will be sent to the Institut Pasteur's research team for studying the impact of the co-culture on nervous cells.

[1] HTLV-1 is a retrovirus that causes a chronic lifelong infection in humans

[2] The secretome refers to all the substances (proteins, cytokines, enzymes, etc.) secreted by a cell or group of cells into their environment.

Return of research results

No individual results of this study will be sent to you, but the overall results of the study will be communicated to you and will be published in a scientific article. This study will bring a collective and public health benefit by enabling a better understanding in the development of HAM/TSP diseases, and thus open up new therapeutic avenues for HAM/TSP illnesses.

The overall results of this study will be made available on the study website SinCeH:
https://research.pasteur.fr/fr/b/16US

These global results may be used in oral or written communications to the scientific and medical community. At no time during these communications will you be identified.

Your personal data: Information and specific rights

What is personal data?

Your personal data, including your health data, will be processed by Institute Pasteur in its capacity as data controller.

Personal data is information about you. This data enables us to know your identity:

- Either directly, through your name or address

- Or indirectly, through the use of a code in place of your identity.

A correspondence table containing your surname, first name, postal address, telephone number and e-mail address, and linking the codes to the identity of the participants, is kept by St Marianna's investigating center. This table will never be passed on to other research teams. It will not be possible to identify you.

This code will be used to replace your identity on all clinical data collected and generated for this study.

Why is your personal data collected and who is responsible for it?

Institute Pasteur as the responsible party will carry out analyses with regard to the purposes presented in this document. This use is possible in accordance with Article 5 and Article 9 of the General Data Protection Regulation (GDPR) as the following conditions are met:

- it is necessary for scientific research purposes

- appropriate measures preserve the confidentiality of your information

- it meets a public health objective and therefore of public interest

What categories of personal data are involved?

Your personal data required for this scientific research are:

- **your demographic** data: age, gender,
- **your health data**: dates, times and results of blood tests : status (asymptomatically infected, ill), rapidity of HAM progression, duration of illness, proviral load

Who will have access to your data?

Your data will be transmitted under conditions adapted to preserve confidentiality:

- to the French health authorities to satisfy an administrative obligation, to other scientific or administrative services for the proper conduct of research

How long will your data be kept for this research?

Data will be kept for the duration of the research, which includes the time required to collect and then analyze the data in order to meet the research objective. This retention period will be 5 years from the date of transfer to the research team of the samples and associated data shown on the web page: https://research.pasteur.fr/fr/b/16US and will be followed by a regulatory archiving period of 15 years after the end of the research. The retention period for research purposes may be increased by 2 years after each publication of the scientific results of this research.

What will happen to your data?

Institut Pasteur may, unless you object:

- re-use your sample and personal data for other research into HAM.

Your data will not be transferred to scientific teams for further research into neurodegenerative diseases for public health purposes and therefore in the public interest.

The site dedicated to the SinCeH project will keep you informed about future studies, and tell you how to object to the re-use of your data and samples https://research.pasteur.fr/fr/b/16US

What are your data protection rights and how can you exercise them?

You can exercise the following rights with regard to your personal data:
- The right to request information about the processing of your data and to request a copy of it (right of access);
- The right to request the rectification of data concerning you if it is inaccurate or incomplete; while we examine your request, you have the right to restrict the processing of your data;
- The right to object to the processing of your data for scientific research purposes at any time and without having to justify your decision;
- If you object to the processing of your data; you may request the deletion of your data already collected when such data is no longer required. However, certain previously collected data may not be deleted if their deletion is likely to make it impossible or seriously compromise the achievement of the purpose of the study or to satisfy a legal obligation.

To exercise your rights as described above, you may contact Institut Pasteur's Data Protection Officer by e-mail, specifying the name of the research concerned (SinCeH), at the following address dpo@pasteur.fr .

If you do not receive a reply within one month, or if you dispute the reply, you have the right to contact the Commission Nationale de l'Informatique et des Libertés (CNIL), the French data protection supervisory authority: CNIL - 3 place de Fontenoy - TSA 80715 -75334 Paris cedex 07 – telephone number : 00 33 1 53 73 22 22 - http://www.cnil.fr .

We thank you for your attention and your participation in our research.