Patient information and consent for participants in pre-screening to a scientific trial for patients with newly diagnosed chronic lymphocytic leukemia

Full title of the study: Short-term combined acalabrutinib and venetoclax treatment of newly diagnosed patients with CLL at high risk of infection and/or early treatment, who do not fulfil IWCLL treatment criteria for treatment. A randomized study with extensive immune phenotyping.

Short Title: PreVent-ACaLL

EudraCT NUMBER: 2019-000270-29

SPONSOR: Rigshospitalet, Copenhagen, Denmark

HOSPITAL NAME:

HOSPITAL ADRESS:

NAME OF INVESTIGATOR:
PHONE NUMBER:

Dear Patient,

Because you are newly diagnosed with Chronic Lymphocytic Leukemia (CLL) we would like to ask your permission to assess if you are at are at high risk of developing infections and/or in need of CLL treatment within the next two years by doing a pre-screening for the medical study called PreVent-ACall.

You yourself decide whether you want to participate. Before you make your decision, it is important to know more about the study. Read through this information letter in your own time. Discuss it with your partner, friends or family. Also read the general brochure on 'Medical research' [insert local/national brochure, if relevant].

The study is supported financially by the Novo Nordisk foundation, and by the company Acerta Pharma.
The study is initiated by the Nordic CLL study groups and the HOVON CLL group and coordinated by Rigshospitalet, Copenhagen, Denmark.

Purpose
Many patients with CLL have a weakened immune system due to their disease. CLL increases the risk of developing serious infections requiring treatment or in the worst case resulting in fatalities. The PreVent-ACaLL study will investigate if a short-termed combination treatment with the drugs venetoclax and acalabrutinib can improve the immune system and thereby reduce the risk of (serious) infections and postpone the need for CLL treatment in patients recently diagnosed with CLL. As half of the patients diagnosed with CLL will not have had a serious infection or CLL treatment within the first 5 years after diagnosis, it is crucial to identify the patients who are at high risk of either infection or CLL treatment.

For this purpose, the machine learning algorithm, CLL-TIM, has been developed to identify patients eligible to participate in the study

Pre-Screening – Assessment of risk of infection

Pre-screening will be done with data already collected as part of the standard of care.
For the assessment of your risk of infection, baseline characteristics, pathology results, prior medical history and medical history including infectious events along with laboratory results will be used. These data will be entered into the CLL-TIM algorithm on a secure server, where your risk of infection will be accessed. In connection with pre-screening it might be necessary to withdraw some blood (max. 30 mL) for analyses that are normally part of standard of care, if these blood tests have not already been done.

High risk of infection

If you are assessed to have a high risk of developing infections or needing CLL treatment within two years, you will be asked if you would like to participate in the PreVent-ACaLL study. You will then get a separate patient information and consent explaining the study thoroughly.

Low risk of infections

If you are assessed to be at a low risk of developing infections or needing CLL treatment within the next two years, you will not be eligible for the PreVent-ACaLL study. However, even if you do not participate in the PreVent-ACaLL trial, as you are not at high risk, we would like to collect information about how you are doing during the duration of the PreVentACaLL study to validate the predictions of the CLL-TIM algorithm.
Data will be collected via local medical record reviews and/or registries for 6-monthly assessment of infectious events, treatment initiation and survival.

Participation in and withdrawal from the study

It is up to you to decide whether to participate in this pre-screening. Participation is voluntary. If you decide not to participate, you will receive the standard of care.
If you do participate in the pre-screening, you can always change your mind and withdraw from the data collection.

Confidentiality

All your data will be treated confidentially. Only the study doctors and the participating staff at the hospital know your identity. All your data in the study will only have a screening ID number. The key linking your identity to the screening ID number remains with the local study doctor. The data cannot be traced back to you from reports and publications about the study. At pre-screening your personal data will be handled in compliance with the Data Protection Act and General Data Protection Regulation. If you have any additional questions, please ask your doctor at your hospital.

Informed Consent

For pre-screening for the scientific study:

PreVent-AcaLL: Short-term combined acalabrutinib and venetoclax treatment of newly diagnosed patients with CLL at high risk of infection and/or early treatment, who do not fulfil IWCLL treatment criteria for treatment. A randomized study with extensive immune phenotyping.

I sign this consent of free will. I understand that by signing this consent I will not lose any rights that I would otherwise be entitled to. I have read and understood the participant information and have received answers to all my questions. I understand that I will receive a signed and dated copy of this consent. I have had the time needed to familiarize myself with the information.

_____
Name of participant (printed)

_____
Signature of the participant

_____
Date

The doctor signing below has fully informed this patient about the above-mentioned pre-screening

_____
Name of the doctor informing the patient (printed)

Signature of the doctor informing the patient

_____
Date