INFORMATION LEAFLET

INTEGRATION OF CLINICAL PHARMACY ALONG THE ENTIRE CARE PATHWAY OF PATIENTS IMPLANTED WITH A PICC-LINE

CLIPICC - RC31/18/0459

VERSION 2 DATED 03/02/2020

Study sponsor: Toulouse University Hospital Center

Acting Principal Investigator: Doctor Elodie CIVADE

Associate Principal Investigator: Doctor Charlotte LABORDE

Madam, Sir,

Your pharmacist has invited you to take part in a research study sponsored by the University Hospital Center of Toulouse. Before making a decision, it is important that you read these pages carefully as they will provide you with the necessary information about the different aspects of this research. Do not hesitate to ask your pharmacist or your doctor any questions you may have. Your participation is voluntary. If you do not wish to take part in this research, you will continue to receive the usual medical care in accordance with current knowledge.

❖ Why this research?

A PICC line is a central catheter or small tube designed to be inserted into a vein. It is placed at the edge of your arm and travels up into a vein that has larger flow. This allows for the administration of certain medications as well as repeated collection of blood samples if necessary. It is an implantable medical device.

Clinical pharmacy is a patient-centered healthcare discipline whose goal is to optimize therapeutic management at every stage of the care pathway. Clinical pharmacy procedures contribute to the safety, relevance and efficacy of drugs and medical devices. To achieve this, pharmacists must work in collaboration with other professionals such as the doctor, nurses, yourself and sometimes caregivers[1].

At present, clinical pharmacy in the field of medical devices (MD) is poorly developed in France. However, it has proven its effectiveness for medications. Thus, we would like to develop clinical pharmacy activities in the context of MDs, starting with the PICC line. We believe that we can improve the quality and safety of your hospital stay and home care through the clinical pharmacy activities detailed below.

❖ What is the purpose of this research?

Your usual treatments will not interfere with the study. You are hospitalized and require a PICC line for medication administration or repeated collection of blood samples. You will then go home with this device. The insertion of this medical device can sometimes lead to certain complications. We would like to show that the intervention of a clinical pharmacist during your treatment can prevent and therefore reduce the number of complications due to PICC lines by interacting with your doctor as needed and by giving you personalized advice on monitoring the PICC line. Similarly, your private nurse, your provider and/or your local pharmacist will receive information to help you follow up and monitor your PICC line.

❖ How is this research going to be carried out?

This is a single-center study at the UHC of Toulouse. Two successive phases are planned with 69 patients each: an observational phase and an interventional phase. Recruitment will last about 12 months to obtain the necessary number of patients.

[1] https://sfpc.eu/presentation/

Depending on when your PICC line is implanted, you may be in the observational phase without clinical pharmacy activities or in the interventional phase with clinical pharmacy activities. You cannot choose which phase you will be in.

- If you are in the **observational phase**:

Your treatment remains unchanged within the framework of standard medical care. We will only collect information without any intervention from the pharmacist. We will call you twice in the week following your discharge and then once a month for a maximum of 3 months.

- If you are in the **interventional phase**:

1. A **pharmaceutical analysis** of the PICC line prescription will be done. We are likely to discuss the prescription with the hospital doctor at this stage. Once the medical device is implanted, we will speak with your hospital nurse to ensure the best possible follow-up.

2. We will have carried **out logistical activities in the operating room where the PICC line is placed.** For example, we will have checked the quantities of devices needed for the installation and their expiry date, and we will also have checked that the lot number of the device is recorded in the hospital's database.

3. Once the PICC line has been implanted, you will return to your hospital ward for further treatment and then return home.

4. **We will analyze your discharge prescription** (medical devices and medicines) and may discuss it with the doctor.

5. You will have a **pharmaceutical discharge interview** of about 20 minutes in your hospital ward. This interview will allow us to discuss your medications and the PICC line with you (what the medications are used for, possible adverse effects, clinical laboratory monitoring if any, etc.). You will be able to ask any questions you may have (medical, clinical, etc.), and we will try to answer them as soon as possible. If further research needs to be done, we will call you to give you the answer. We will give you **information documents** on the PICC line to help you monitor it and be aware of the signs that you to the need to talk to a health professional as soon as possible. The goal is to prevent the most common complications. Finally, we will give you a sheet with the lot number of your PICC line so that you will have information about the implantation of this device in your possession. French law requires this.

6. A private nurse will redo your dressings at home. We will ask you to give us his or her name so we can contact him or her during the study. We will provide your nurse with your PICC line **information booklet** as well as **information on how to monitor and maintain** your PICC line.

7. We will ask you for the contact details of your pharmacist and your general practitioner so that we can contact them if necessary and in case of complications following insertion of the device. We will forward the **discharge prescription** to your pharmacist to ensure optimal **continuity of care**. We can also send him/her information about the PICC line.

8. Follow-up calls are scheduled throughout the study to **monitor and optimize your care**:

   8.1. You will be called personally by a pharmacist to follow-up on your treatment. We will ask you questions about the care of the dressing and about any complications. These calls will take place approximately on the 3rd and 7th day after the implantation and after 1 month, 2 months and 3 months. These calls will last approximately 15 minutes.
   8.2. Your nurse will also be called **to follow-up** on your care. We will ask him/her the same questions as you about the dressing and any complications. **Pharmaceutical advice** will be given if necessary to improve your care in collaboration with your private nurse. These calls will take place approximately on the 3rd and 7th day of the dressing care and after 1 month, 2 months and 3 months.
   8.3. Your local pharmacist will be contacted if necessary to note any changes in your treatment.

8.4. Your general practitioner will be contacted at the end of the 3-month follow-up period or earlier if necessary in the event of complications. Indeed, he/she is the one who knows your history best (in the event of a new medical condition or other diagnosis).

❖ **Who can participate?**

You can participate when all the following criteria are met:

- You are an adult, 18 years of age or older
- You are affiliated with the French social security system
- You live at home and can be reached by telephone
- You are scheduled to undergo insertion of a PICC line and you are destined to return home with this PICC line implanted
- Your profile suggests that your discharge prescription will include medications and a MD

You cannot be included if:

- You are a minor, under the age of 18
- You are not affiliated with the French social security system
- You do not live at home
    - You are institutionalized (specialized institutions)
    - You are living in a facility for dependent elderly persons
    - You live in a nursing home
    - You benefit from HAH (hospitalization at home)
- Your current health condition does not require a PICC line
- Your profile suggests that your discharge prescription will not include associated medications and MDs
- Your treatment plan does not include returning to home

Participation is voluntary. You will not be compensated for participating in this study.
No further examination is necessary before inclusion, only those corresponding to your treatment will be carried out.

❖ **What will you be asked to do?**

At the time of your inclusion, regardless of the phase:
We will ask you for your contact details and those of your GP and your pharmacist.

After the implantation of the PICC line, regardless of the phase:
We will ask you for the contact details of your private nurse who will monitor you at home.

Once you have returned home:
We will call you on the 3rd and 7th day after the implantation and 1 month, 2 months and 3 months after the implantation to:

- Gather information on the care of your dressing
- Collect information about possible complications due to the presence of the PICC line:
    - Related to your skin: any pain, redness or swelling
    - Related to the medical device: the catheter may become clogged, slightly cracked or displaced

We remind you that these events are relatively rare.

This phone call will last about 15 minutes.
If necessary, this information will be compared with the information given by your local healthcare professionals (doctors, nurse, healthcare provider and pharmacist) to confirm it.
If you are still hospitalized in the days following the insertion of the PICC line, we will visit you in your room on the 3rd and 7th day after the insertion.
You can withdraw from the study at any time.
If you withdraw from the study, you will continue to receive your current care.

❖ **What are the expected benefits?**

For you, the benefits are as follows:

- Due to additional information about your care and coordination between professionals, we believe you will benefit in the following ways:
  - Better care in the hospital and back home
  - Fewer complications due to the PICC line and associated medications
  - Your PICC line will be more comfortable, thanks to the care and maintenance tips
  - Improved quality of life, and better satisfaction with your care
- You will also have documents to refer to if you have any questions and you can always contact the hospital pharmacist and your local health care professionals if necessary
- We offer a close follow-up and a privileged relationship thanks to regular telephone calls

This research does not expose you to any additional risk in your care.

For science: clinical pharmacists offer a new way of working by accompanying you from when the medical device is implanted in the operating room to when you are at home by working more closely with hospital professionals and with healthcare professionals outside the hospital.

❖ **What are the possible constraints?**

You will be called five times after the insertion of your PICC line according to the research protocol, after you return home. Each phone call will last approximately 15 minutes. This call could disrupt your day, your work, and your activities. At any time, you can tell the person whose is calling you to call you back at a more convenient time.

❖ **What are the possible medical alternatives?**

If you do not participate in the research, you do not lose any chance of treatment.
You benefit from the usual care and standard practices in accordance with current knowledge.

❖ **What are the medical treatment modalities?**

If you are excluded from the research, you will be informed and you will continue to benefit from the usual medical care.

If the study is discontinued, the reason for the discontinuation will be noted. Your data will be used in the statistical analysis of the group you were in at the time of your study participation.
At the end of the study, the results will be communicated to you if you wish.

❖ **What are your rights?**

Your hospital pharmacist must provide you with all the necessary explanations about this research. If you wish to withdraw from the study at any time, no matter the reason, you will continue to benefit from medical follow-up and this will not affect your future care.

In the context of the research in which the Toulouse University Hospital offers you the opportunity to participate, your personal data will be processed electronically to enable the results of the research to be analyzed in the light of the research objective presented to you.
The party responsible for data processing is the UHC of Toulouse. The study investigator and other study staff will collect information about you, your health, your participation in the study, and, if applicable, your lifestyle. This information, called "Personal Information", is recorded on forms, called case report forms, provided by the sponsor. Only the information necessary for the processing and aim of the research will be collected. This data will be kept for the duration of the study until the final report or until the last publication and then archived in accordance with current regulations. To ensure the confidentiality of your personal information, neither your name nor any other information that would allow you to be identified directly will be entered in the case report form or in any other file that the study pharmacist will provide to the sponsor or the sponsor's authorized

representatives. Only a code and your initials will identify you. The code is used so that the study pharmacist can identify you if necessary.

In accordance with the provisions of the French Data Protection Act (Act No. 78-17 of January 6, 1978 on Data Processing, Data Files and Individual Liberties as amended by Act No. 2018-493 of June 20, 2018 on the Protection of Personal Data) and the General Data Protection Regulation (EU Regulation 2016/679), you have the right to access and rectify your personal information. In certain cases, you may also request that the processing of your personal information be restricted, object to certain types of processing of your personal information, and request that your personal information be deleted. However, certain data that was previously collected may not be erased if such deletion is likely to make it impossible or seriously compromise the achievement of the research objectives. You may exercise these rights by making a written request to the study investigator. The sponsor will respond to your request to the extent possible in accordance with its other legal and regulatory obligations and when required by law.

The sponsor may share personal information with regulatory agencies or research partners. These persons, companies and agencies may be in your country, in other EEA countries, or in other countries outside the EEA. Some non-EEA countries may not offer the same level of privacy protection as your country. The Sponsor will, however, maintain the confidentiality of all personal information it receives to the fullest extent possible within the limits of the law. The Sponsor will adopt appropriate contractual measures, including its certification under the Privacy Shield and its standard data protection clauses, to ensure that recipients outside the EEA provide an adequate level of protection for your personal information as set out in this form and in accordance with the law.

You also have the right to object to the transmission of data covered by professional secrecy that may be used during this research and processed. You can also access directly, or through the intermediary of the doctor of your choice, all your medical data pursuant to the provisions of Article L1111-7 of the French Public Health Code. These rights are exercised with the doctor or pharmacist who follows you in the context of the research and who knows your identity.

The competent authorities and the sponsor or its authorized representatives may also need access to your medical records and your study file to verify the data collected in the context of the study.

Your coded personal information may be used for further scientific research on your disease or other diseases in accordance with applicable laws and regulations.

If you have any additional questions about the collection or use of your personal information or the rights associated with this information, please contact the Data Protection Delegate of the UHC of Toulouse *(DPO@chu-toulouse.fr)* or the study investigator.

If you feel that your rights are not being respected, despite the measures put in place by the sponsor, you may file a complaint with the competent data protection supervisory authority in your country of residence (the CNIL for France).

In accordance with the French law No. 2012-300 of March 5, 2012 relating to research involving humans:

- This research has obtained a favorable opinion from the Committee for the Protection of Persons (CPP Sud Est 6).
- The sponsor of this research, the UHC of TOULOUSE has taken out civil liability insurance with Lloyd's Insurance Company S.A.
- This research falls within the framework of the Reference Methodology MR-001 of the CNIL (French National Commission for Information Technology and Civil Liberties)
- Persons who have suffered harm because of their participation in this study may assert their rights before the regional conciliation and compensation commission for medical accidents.
- When this research is completed, you will be kept personally informed of the results by the Investigator as soon as they are available, if you want.

After reading this information leaflet, do not hesitate to ask the investigator any questions you may have. After a waiting period, if you agree to participate in this research, you must complete and sign the Consent Form. A copy of the completed document will be given to you.

Thank you for your attention.

CONSENT FORM

INTEGRATION OF CLINICAL PHARMACY ALONG THE ENTIRE CARE PATHWAY OF PATIENTS IMPLANTED WITH A PICC-LINE

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VERSION 2 OF 03/02/2020

Research sponsor: Toulouse University Hospital Center

Acting Principal Investigator: Doctor Elodie CIVADE

Associate Principal Investigator: Dr. Charlotte LABORDE

I, the undersigned..... (surname, first name) hereby certify that I have read and understood the information leaflet that was given to me.

I was able to ask any question I needed to ask to the investigator, Elodie CIVADE, who explained to me the nature, objectives, potential risks and constraints related to my participation in this study.

I am aware of the possibility that I may interrupt my participation in this study at any time without having to justify my decision and I will do my best to inform the pharmacist who is following me in the study. Of course, this will not affect the quality of subsequent care.

I have been assured that the decisions that are necessary for my health will be made at any time, in accordance with the current state of medical knowledge.

I have been informed that some of the information gathered during this study may be retained for future research purposes. I have also been informed of my right to object to such retention and subsequent use for research purposes.

I am aware that this study has received the favorable opinion of the Comité de Protection des Personnes Sud Est 6 and falls within the scope of MR001 of the Commission Nationale Informatique et Libertés (CNIL).

The sponsor of this study (CHU de Toulouse, 2 rue de Viguerie, 31000 Toulouse) has taken out a civil liability insurance policy in case of harm with Lloyd's Insurance Company S.A (BARCET 19001).

I accept that the persons collaborating in this study or authorized by the sponsor, as well as potential Health Authority representatives, have access to the information in the strictest confidentiality.

I accept that the data collected during this study may be subject to computerized processing under the responsibility of the sponsor.

I have noted that, in accordance with the provisions of the law on data processing, data files and freedoms and the general regulations on data protection, I have the right to access, rectify and delete data, to limit processing and to make the data portable. I also have a right to object to the transmission of data covered by professional secrecy which may be used in the context of this study and processed. These rights are exercised with the pharmacist who is following me in the context of this study and who knows my identity.

My consent in no way relieves the investigator and the research sponsor of their responsibilities towards me. I retain all legal rights.

The results of the study will be communicated to me directly, if I so wish, in accordance with the French law of 4 March 2002 on the rights of patients and the health care quality.

Having had sufficient time for thought before making my decision, I freely and voluntarily agree to participate in the CLIPICC study.

I may at any time request additional information from the pharmacist who has invited me to participate in this research, telephone number: 05 67 77 11 15 or 05 67 77 12 14

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Patient's signature:

Investigator's signature: