Full research title:
Infrared illumination for difficult peripheral venous catheterisation in critically ill adult patients: a prospective, randomised, multicentre trial (ICARE).

This research is being promoted by the Assistance Publique - Hôpitaux de Paris Clinical Research and Innovation Delegation.
1 avenue Claude Vellefaux
75010 Paris

PATIENT INFORMATION

Dear Sir/Madam

You have been admitted to intensive care following a deterioration in your health.
The doctor/professor/nurse (delete as appropriate)..... (name, first name), working in the hospital ..... invites you to take part in a research study entitled "Infrared illumination for difficult peripheral venous catheterisation in critically ill adult patients: a prospective, randomised, multicentre trial (ICARE)".
It's important that you read this notice carefully before making your decision. Don't hesitate to ask for clarification.
If you decide to take part in this research, you will be asked to give your written consent.

1) What is the aim of this research?

This research focuses on the use of infrared light (infrared illumination) for the placement of "intravenous infusions" (peripheral venous catheterisation) in difficult-to-perfuse critically ill patients. Peripheral venous catheterisation is very important in the management of critically ill patients, for example to administer rescue medication. Difficulty in perfusing critically ill patients is common when using the usual technique (visual location and palpation of veins).
Infrared illumination uses a simple device (AccuVein AV 500®), which is completely risk-free and contact-free, to enable the nurse to see superficial veins more easily. It has improved the success of peripheral catheterisation in difficult-to-perfuse children, but has never been tested in the intensive care setting. We hypothesised that infrared illumination could improve the success of peripheral venous catheterisation in difficult-to-perfuse critically ill patients to speed up the management of life-threatening emergencies.

To answer the research question, 460 patients admitted to intensive care units in hospitals in France will be included.

2) What does research involve?

The proposed research will evaluate the benefits of using infrared light (AccuVein®) to improve the success and quality of peripheral venous catheterisation and reduce complications.

3) What is the research timetable?

The expected duration of the research is 55 months and your participation will last 3 days.

After your enrolment, you will be randomly assigned to use the usual technique or infrared light for your peripheral venous catheterisation. This randomisation will take place on the first day of the study (D1).
From D1 to D3 (during your hospital stay), the usual management of your condition, including monitoring, will remain unchanged.

4) What are the benefits of participating?

Patients in this study will benefit from standardised peripheral venous catheterisation according to recommendations. The benefit is expected to be an increase in the success and quality of peripheral venous catheterisation and a reduction in complications associated with peripheral venous catheterisation.

5) What treatments are authorised and what are not?

All treatments are authorised.

6) What are the foreseeable risks and constraints added by the research?

There are no foreseeable risks associated with the research. The AccuVein AV500® device is already in use in many hospitals in France and abroad. It provides additional information (better visualisation of the veins) without any risk to the patient.

If you agree to take part in this research, you must respect the following point
- Be affiliated to or a beneficiary of a social security scheme.

8) What are the possible medical alternatives?

If you refuse to take part in the research, you will continue to receive usual care appropriate to your condition.

9) What are the arrangements for medical care at the end of your participation?

There are no specific follow-up requirements for the study. You will continue to receive care appropriate to your condition if the study is stopped early or if you stop participating.
Your doctor (or nurse) may decide to stop your participation at any time and will explain the reasons to you.

10) If you take part, what will happen to the data collected for research purposes?

As part of the research in which the AP-HP proposes that you participate, your personal data will be processed in order to enable the results of the research to be analysed in the light of the objective of the research presented to you.
To this end, your medical data will be communicated to the promoter or to persons or partners acting on its behalf in France and will be kept for up to 2 years after the last publication of the results of the research. These data will be identified by a registration number. These data may also be communicated to the French health authorities under conditions that ensure confidentiality.

Your medical data, which may be used by the competent authorities to document a case involving the infrared light evaluated in this research, may be transferred to an industrial company so that a greater number of patients may benefit from the results of the research. This transfer will take place under conditions that guarantee confidentiality.

Your data may be used for further research or analyses complementary to this research, in collaboration with private or public partners, in France or abroad, under conditions guaranteeing confidentiality and the same level of protection as required by European legislation.
You may withdraw your consent to the further use of your data at any time by contacting the doctor (or nurse) treating you as part of this research.

The computer file used for this research has been implemented in accordance with French regulations (Data Protection Act, as amended) and European regulations (General Data Protection Regulation - GDPR). You have the right to access, rectify and object to the processing of data covered by professional secrecy and used in the context of this research. These rights can be exercised with the doctor (or nurse) in charge of the research, who is the only person who knows your identity (identified on the first page of this document).

In the event of termination of participation, data collected prior to termination will be used in accordance with the regulations and exclusively for the purposes of this research. Deletion of the data could compromise the validity of the research results. In this case, your data will not be used subsequently or for any other research.

If you have any difficulties in exercising your rights, you can contact the AP-HP Data Protection Officer at the following address: protection.donnees.dsi@aphp.fr, who will be able to explain the remedies available to you before the CNIL.

11) How is this research supervised?

The AP-HP has taken all necessary measures to conduct this research in accordance with the provisions of the Public Health Code applicable to research involving human subjects.

The AP-HP has taken out an insurance policy (**N° 0100518814033 190060**) with the company BIOMEDICINSURE, whose address is Parc d'Innovation Bretagne Sud C.P.142 56038 Vannes Cedex, covering its civil liability and that of all the parties involved.

The AP-HP received a favourable opinion for this research from the Comité de Protection des Personnes (**CPP IDF1-Hotel-Dieu) on 11/06/2019.**

12) What are your rights?

Your participation in this research is completely free and voluntary. Your decision will not affect the quality of care and treatment you have a right to expect.

Throughout the research process, you will be able to ask your doctor (or nurse) for information about your health and for explanations about the research process.

You can withdraw from the research at any time without giving a reason and without any consequences for the continuation of your treatment or the quality of care you receive, and without any consequences for your relationship with your doctor (or nurse). Once you have withdrawn, you may continue to be followed by the same medical team. In this case, the data collected up to the time of withdrawal will be used to analyse the results of the research.

Your medical record will remain confidential and can only be consulted under the responsibility of the doctor (or nurse) in charge of your treatment, by the health authorities and by persons duly authorised by the AP-HP for research purposes and subject to professional secrecy.

At the end of the research and after the data relating to this research have been analysed, you may be informed of the overall results by requesting this from the doctor (or nurse) treating you as part of this research. You may also have access to all your medical data, either directly or through a doctor (or nurse) of your choice, in accordance with the provisions of article L 1111-7 of the French Public Health Code.

Once you have read all this information, discussed all aspects with your doctor (or nurse) and been given time to think, if you agree to take part in the research, you will be asked to sign and date the informed consent form at the end of this document.

ASSISTANCE PUBLIQUE HÔPITAUX DE PARIS

CONSENT FORM

I, the undersigned, Mrs, Mr [delete as appropriate] (name, first name).....
voluntarily agree to participate in the research study entitled
" Infrared illumination for difficult peripheral venous catheterisation in critically ill adult patients: a prospective, randomised, multicentre trial (ICARE)".
organised by the Assistance Publique - Hôpitaux de Paris and offered to me by the doctor / professor / nurse
(name, first name, telephone number of the investigator in this study)

- I have read the information note **version 4.0 dated 27/11/2023 [3 pages]** which explains the purpose of this research, how it will be carried out and what my participation will involve;
- I will keep a copy of the information note and the consent form;
- I was given the right answers to all my questions;
- I have had enough time to make my decision;
- I understand that my participation is voluntary and that I can stop at any time without incurring any liability or affecting the quality of care I receive;
- I have been informed that the data collected as part of the research may be used for other research and that I may object at any time;
- I understand that my participation may be interrupted by the doctor (or nurse; if necessary, he/she will explain the reasons;
- Before taking part in this research, I have had a medical examination tailored to the research, the results of which have been made available to me.
- I understand that in order to participate in this research, I must be a member of or a beneficiary of a social security scheme. I confirm that this is the case;
- I have been informed that my participation in this research will last 3 days and that this means that I cannot consider taking part in any other research without informing the doctor (or nurse) treating me for the research;
- My consent in no way relieves the doctor (or nurse) who is treating me for the research, nor the AP-HP, of any of their responsibilities and I retain all my rights as guaranteed by law.

Signature of the person taking part in the research		**Signature of doctor or nurse**	
First name :		First name :	
Date	Signature :	Date	Signature :

This document must be drawn up in 3 copies, the original of which must be kept for *15 years* by the investigator, the second given to the person giving consent and the third sent to the AP-HP in a sealed envelope at the end of the research.