Prospective randomized study for the prevention of seroma after axillary dissection for breast cancer with the use of cyanacrylate glue (Glubran2®)

Information for the patient

Dear Sir/Madam, You have been informed by your doctor that you suffer from breast cancer for which you require surgery. The type of surgery you are a candidate for and your current clinical condition expose you to a high risk of prolonged serum leaks called seroma. Prolonged seroma is the most common complication after axillary surgery. They lead to an increase in drain maintenance times, associated with greater postoperative pain, decreased postoperative mobility, and increased risk of infections, resulting in prolonged hospitalization. In order to prevent or reduce the incidence of post-operative seromas, several intraoperative techniques and surgical sealants have been developed. A clinical trial is underway in our center regarding the treatment of patients with health conditions similar to yours. Before asking you to participate, so that you can decide in full awareness and autonomy, we provide you with some information below. Please read this document carefully and, if you wish, discuss it with other people, taking all the time you need and we invite you to ask us for clarifications or clarifications if you need them. We will discuss the contents of this information sheet with you, of which we will provide you with a copy. If you decide to participate in the trial, you will have to sign a consent form. As required by law, the clinical study we are proposing has been reviewed and approved by the competent Ethics Committee and other relevant authorities and will be conducted in compliance with the Declaration of Helsinki, the Standards of Good Clinical Practice and all current legislation on the matter of clinical trials. The study is promoted by the National Cancer Institute of Naples and is carried out in the facility where you are being treated under the responsibility of Dr Raimondo di Giacomo.

The study we are proposing involves the use of Glubran2® glue on the axillary cable. The main objective of the Study is to confirm and verify the effectiveness of Glubran® 2 in the prevention/reduction of seroma after breast conserving surgery or mastectomy and ipsilateral axillary dissection in patients affected by breast cancer. To guarantee maximum correctness in carrying out the study, in the interests of the patients participating, it is necessary that the choice of offering each individual patient both treatments (use of Glubran2® glue) or only the standard surgical technique (without the use of Glubran2® glue), is taken according to a random mechanism managed by a computerized system (randomization). In this way, if you decide to participate, you will have a 50% chance of receiving only the standard surgical technique and a 50% chance of receiving in addition the use of Glubran2® glue on the axillary cable. Since the decision on the assignment of treatment will be made the day before the operation, you will not know which treatment will be given to you, nor will it be made known to you afterwards, in order not to influence the evaluations of the outcome of the treatment. A total of 200 patients will be enrolled in this study. Your doctor will provide you with all the details regarding the surgical procedure you will receive and the risks associated with it, and will also be able to provide you with all the information you want on the conventional surgical techniques used that may be indicated in your case. The use of Glubran2®, based on the data available in the literature, does not entail any particular additional risks for your health.

From participation in this study we hope that you will obtain a benefit in terms of improvement in your health, although we cannot guarantee that this will occur; consider, however, that the information obtained from this research, also thanks to your participation, will help us to better understand the procedure under study and your pathology and therefore could be useful, in the future, for other patients affected by the same disease as you who

undergo the same type of surgery. If during the conduct of the clinical study new information emerges regarding the risks and benefits of the proposed treatment, which could possibly change your willingness to participate in the study, it will be promptly reported to you by the doctor in charge of the study. It is important that you are aware of the fact that:

• your decision to participate in this study is completely voluntary and must be taken freely, based on the information contained in these pages, as well as any other information that you wish to ask your doctor;

• if you refuse to participate in this study you will still be treated at this center (if you want it) and the quality of the assistance provided to you will not be modified in any way; in this case you will be offered the treatment considered most appropriate based on available knowledge;

• even after having given your consent, you can at any time decide to withdraw from the study without having to provide any justification and without this modifying in any way the assistance you will receive;

• you will be immediately informed of any circumstances that may change your willingness to participate in the trial.

• In the event of damage suffered due to the drug or the study procedures, the promoter is insured for compensation for civil liability damages benefiting from the insurance coverage of the National Cancer Institute of Naples. The doctor in charge of the study, who you should contact in such situations, can give you more detailed information on the matter. If anything in this information form is not clear to you, or if you have any doubts, do not hesitate to ask your doctor for explanations. If you agree to collaborate in the study, please complete the form on the following page. We thank you for your cooperation.