GANEA 3

Ganglion sentinelle Après chimiothérapie NEoAdjuvante dans le cancer du sein

Phase : Sans

Type d'essai : Académique / Institutionnel

Etat de l'essai : Ouvert

Objectif principal

The primary objective is to evaluate the interest of identifying, before NAC, the initial involved lymph node to improve the prediction of axillary status after NAC.

Objectifs secondaires

To assess the feasibility, at the time of the surgery, of the identification and resection of the initially involved lymph node, tagged with the metal clip before NAC.
To evaluate the complications related to the setting up of the metal clip for the identification of a lymph node metastatic.
To evaluate the interest and impact of immunohistochemical analysis of tagged lymph node and SLN.

Résumé / Schéma de l'étude

Experimental : Tagged axillary metastatic node.
Patients undergo axillary sonography assessment routinely performed to seek suspicious nodes. A cytological examination (biopsy is optional) of the suspicious node is performed.
The involved node is then tagged with a metal clip under sonography. Then, patients receive NAC before surgery. Breast surgery (conservative or radical) and axillary surgery are performed during the same procedure, 4 to 6 weeks after completion of NAC.

Critères d'inclusion

1 Patients ≥ 18 years old.
2 Initial diagnosis of operable invasive breast carcinoma.
3 Histologically proven axillary metastasis (cytology or biopsy) before NAC.
4 Patient included in a therapeutic approach of neoadjuvant chemotherapy.
5 Procedure for the detection of sentinel lymph node by isotopic method +/-.
6 Information of the patient and obtaining written consent, signed by the patient investigator.
7 Affiliated patient or beneficiary of the social security.

Critères de non-inclusion

1 pT4d (inflammatory breast cancer).
2 Metastatic breast cancer.
3 Any prior chemotherapy for contralateral breast cancer.
4 Local relapse of breast cancer.
5 Axillary metastasis not histologically proven before NAC.
6 Allergy known to the 2 detection products (Blue and radioactive tracer).
7 Pregnant or lactating woman.
8 Neo Adjuvant chemotherapy contraindicated.
9 Patient protected or under guardianship or unable to give consent.
10 Impossibility of submitting to the medical examination for geographical, social psychological.

Calendrier prévisionnel

Lancement de l'étude : Janvier 2019
Fin estimée des inclusions : Octobre 2022
Nombre de patients à inclure : 385

Etablissement(s) participant(s)

> Centre Antoine Lacassagne (CAL)

(06) ALPES-MARITIMES

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