

## CAPTRANE - (dernière mise à jour : 10/07/2019)

[ARCHIMAIIDindex.php?action=show&id=723](http://ARCHIMAIIDindex.php?action=show&id=723)

### Informations générales

**Titre de l'étude** : Etude multicentrique, ouverte, randomisée, comparant le traitement topique par patch de capsaïcine à 8% (Qutenza) à la Prégabaline per os dans le traitement précoce des névralgies inter costo brachiales après une chirurgie primaire pour cancer du sein

**Traitement** : Chirurgie

**Type d'étude** : Hors ciblage moléculaire

**Phase** : III      **Stade** : Localisé à Métastatique      **Ligne(s)** : 1

**Schéma** : Breast cancer is the most common cancer in women in Europe. Therefore, breast cancer has become a chronic disease and patients need to learn to live with it as well as with the adverse effects related to the disease itself or to the therapies used.

As noted in the third "Plan cancer", pain is a major criterion in the quality of life of patients treated for breast cancer.

Neuropathic pain was defined in 2011 by the international Association for the Study of Pain (I.A.S.P.) as the direct result of a lesion or disease affecting the somato-sensory system.

Surgical treatment is often the first treatment of breast cancer. It can be conservative by performing a partial mastectomy (lumpectomy or quadrantectomy) or non-preservative by total mastectomy.

Intercostobrachial neuralgia (NICB) or Post mastectomy painful Syndrome (MPRR) was first described by Wood in 1978 as "chronic pain beginning immediately or early after a mastectomy" Or a lumpectomy affecting the anterior thorax, armpit and/or arm in its upper half. These post-surgical pains are related to a lesion of the nerves in the breast area.

In particular, the intercostobrachial nerve can be severed, stretched or crushed during surgery.

Post-operative neuropathic pain in patients with breast cancer is underdiagnosed either by general practitioner or in a specialized environment.

The diagnosis of neuropathic pain is performed during examination and clinical examination. Several scales allow to detect neuropathic pain but only the DN4 is recognized to be the most specific and sensitive scale.

Patients do not always express this pain. They do not always reconcile with the surgery. Either because the pain occurs a long time after the surgery, or they find it normal to get hurt. These diagnostic difficulties cause a delay in setting up a suitable analgesic treatment.

However, neuropathic pain responds poorly to common analgesics. Diagnosis, evaluation and early management of neuropathic pain are a priority in order to avoid their chronicization, to improve the quality of life of patients with breast cancer and to enable them to return to work quickly.

We therefore assume that the diagnosis of early neuropathic pain at 2 months of surgery associated with initiation of appropriate topical treatment without the systemic effects of conventional oral treatments, would reduce the incidence of Chronic neuropathic pain 6 months after surgery.

### Spécialités / Localisations

**Spécialité n°1** : Seins, organes génitaux de la femme

**CIM10 - Localisation n°1** : C50 - Tumeur maligne du sein

### Critères

**Critères d'inclusion** : - Male or female who had first breast cancer surgery, regardless of the type of surgery

- Age  $\geq$  18 years
- Healthy, non-irritated skin on painful areas to treat
- During the inclusion visit to M4 post surgery, neuropathic pain of the breast and / or axillary area corresponding to inter-brachial neuralgia with a DN4 $\geq$ 4 score.
- Obtaining the signed written consent of the patient
- Major patient affiliated to a social security scheme

**Critères de non-inclusion** : - Contraindications specific to the treatments studied : capsaicine and pregabalin

- Diabetic patient
- Previous treatment with capsaicin or pregabalin
- Opioid treatment  $>$  80 mg / day (oral morphine equivalent) in progress- Topical treatment of pain between surgery and inclusion visit
- Uncontrolled hypertension (systolic blood pressure  $\geq$  180 mmHg or diastolic blood pressure  $\geq$  90 mmHg) or recent history ( $<$ 3 months) of cardiovascular events (stroke, heart attack, pulmonary embolism)
- Creatinine clearance (CLcr)  $<$ 60mL / min according to the Cockcroft-Gault formula
- Pregnant woman, likely to be pregnant or breastfeeding
- Persons deprived of their liberty or guardianship (including curators),
- Impossibility of submitting to the medical follow-up of the test for geographical, social or psychological reasons

## Informations promoteur

**Nom du promoteur** : INSTITUT DE CANCEROLOGIE DE L'OUEST

**Type de promoteur** : Institutionnel

**Adresse** : INSTITUT DE CANCEROLOGIE DE L'OUEST - 44000 NANTES

**Coordonnateur** : - *Mail* : - *Tél* :

## Informations centre investigateur n°1

**Nom du centre** : Centre Hospitalier de Valenciennes

**Adresse** : Avenue Désandrouin 59300 VALENCIENNES

**Investigateur** : Docteur Antoine LEMAIRE

**TEC / ARC / IDE** : Madame Marielle FERY - *Mail* : fery-m@ch-valenciennes.fr - *Tél* : 03 27 14 07 15

**Ouverture de l'essai** : OUVERT

## Informations centre investigateur n°2

**Nom du centre** : Centre Oscar Lambret

**Adresse** : 3 Rue Frédéric Combemale 59000 LILLE

**Investigateur** : Docteur Abesse AHMEIDI

**TEC / ARC / IDE** : Unité Intégrée de Recherche Clinique - *Mail* : [investigation@o-lambret.fr](mailto:investigation@o-lambret.fr) - *Tél* : 03.20.29.59.35

**Ouverture de l'essai** : OUVERT

## Liens utiles

**ClinicalTrials.gov (anglais)** : <https://clinicaltrials.gov/ct2/show/NCT03794388>