EQUIVOK - (dernière mise à jour : 20/01/2020)

http://archimaid.fr/index.php?action=show&id=136

Informations générales

Titre de l'étude : Etude prospective évaluant l'impact du résultat du profil génomique ARN, défini par un test génomique, sur la décision de traitement de patientes présentant une tumeur mammaire Her 2 équivoque par technique ISH

Traitement : Adjuvant

Type d'étude : Hors ciblage moléculaire

Phase : NA **Stade** : Localisé à Localement avancé **Ligne(s)** : 1

Schéma : The American Society of Clinical Oncology (ASCO) and the /College of American Pathologists (CAP) recommend that HER2 status (negative or positive) must be determined in all patients with invasive breast cancer. The knowledge of HER2 status will help the oncologist in prescribing or not a HER2-targeted therapy to patients. Presently, two main methods are used to assess HER2 status: immunohistochemistry (IHC, protein expression) and in situ hybridization (ISH, gene expression) in order to classify tumor sample as positive, negative or equivocal. When a tumor is classified HER 2+ by IHC method, a second test is performed using ISH methods (FISH, SISH, CISH). In case of HER2 equivocal result with ISH method (4 ?HER2 gene number copy <6), the patient is eligible to an anti-HER2 therapy after discussed during MD-MM. This decision should be individualized on the basis of patient status (comorbidities and prognosis) and patient preferences after discussing available clinical evidence.

Based on molecular classification, RNA expression could help to discriminate breast cancer subtypes (luminal A, luminal B, HER2-overexpressed and triple negative). Prosigna is a genomic test, developed by NanoString® based on the PAM50 gene signature, which measures the expression of 50 genes to classify tumors into 1 of 4 intrinsic subtypes and could allow determining the HER2 status.

This study was designed in order to define if such a test could help the oncologist to define the better therapeutic decision in a HER2 equivocal population. In addition, concordance tests will be performed. The aim of this study is to assess the modification decision rate between the first and the second multidisciplinary decision-making meeting in HER2 equivocal patients using genomic testing.

1 arm:
- Experimental: Use of PAM 50 test in Her2 equivocal breast cancer patient
Patients with an equivocal-HER2 breast cancer (IHC Score 2 and equivocal ISH defined as HER2/Chr17 ratio <2 and 4 ?HER2 gene number copy < 6) will be eligible for RNA genomic test (PAM 50 test).

Spécialités / Localisations

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

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

Critères

Critères d'inclusion : - Female
- Age >= 18 ans
- Performance status <= 2 (according to WHO criteria)

- Patient with early invasive breast cancer histologically confirmed stage I to IIIA)
- Positive or negative lymph node involvement
- Positive or negative Hormonal Receptors (Estrogens and/or Progesterone),
- Equivocal HER2 status (IHC Score 2 and equivocal ISH defined as HER2/Chr17 ratio <2 and 4 <= HER2 gene number copy < 6) as assessed on surgical specimen
- Adequate Hematological, Hepatic, Renal and Cardiac Functions
- Patient potentially eligible for an anti-HER2 therapy
- Patient eligible to receive an adjuvant therapy
- Signed Informed Consent
- Patient with social insurance.

Critères de non-inclusion : - Non-measurable tumor
- Unknown Hormonal Receptors
- Unknown node involvement
- Positive or negative HER2 status (Score 0, 1 or 3 IHC, or Negative or positive ISH)
- Disease stage >=IIIB
- Patient not able to follow the trial.

Informations promoteur

Nom du promoteur : Centre Jean Perrin

Type de promoteur : Institutionnel

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Informations centre investigateur n°1

Nom du centre : Centre François BACLESSE

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Ouverture de l'essai : CLOS

Liens utiles

ClinicalTrials : https://clinicaltrials.gov/ct2/show/NCT03197805?titles=equivok&rank=1