GEMPAX - PRODIGE 65-UCGI36 (dernière mise à jour : 22/11/2019)

http://archimaid.fr/index.php?action=show&id=944

Informations générales

Titre de l'étude : Etude de phase III randomisée évaluant gemcitabine plus paclitaxel versus gemcitabine seule après échec ou intolérance au FOLFIRINOX dans l'adénocarcinome pancréatique canalaire métastatique

Traitement : Métastatique ou localement avancé

Type d'étude : Hors ciblage moléculaire

Phase : III **Stade** : Métastasique **Ligne(s)** : 2

Schéma : This study aims to evaluate whether the combination of gemcitabine and paclitaxel allows to improve the overall survival compared to gemcitabine alone, in patients with metastatic Pancreatic Ductal Adenocarcinoma (PDAC) after FOLFIRINOX failure or intolerance.

2 treatment arms:
- Experimental: GEMPAX
Gemcitabine + Paclitaxel until progression
- Active Comparator: Control
Gemcitabine alone until progression

Spécialités / Localisations

Spécialité n°1 : Organes digestifs

CIM10 - Localisation n°1 : **C25** - Tumeur maligne du pancréas

Critères

Critères d'inclusion : - Metastatic Pancreatic Ductal Adenocarcinoma with histological or cytological proof
- Age >=18 years
- At least 1 evaluable lesion according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 outside any previously irradiated area
Failure of first line FOLFIRINOX (Progressive disease during therapy of within 3 months)
- Eastern Cooperative Oncology Group (ECOG) Performance Status <=2
Life expectancy >=12 weeks
- Negative serology (HIV, hepatitis B and C)
- Adequate organs function
- Proven Post-menopausal status or negative urinary or serum pregnancy test
- Woman of childbearing potential and male patients must agree to use adequate contraception fo the duration of the trial and up to 6 months after completing treatment
- Patients affiliated to the social security system
- Patient must have signed a written informed consent form

Critères de non-inclusion : - Any other primary tumor or secondary malignancy except basal cell carcinoma of skin or in situ carcinoma of the cervix uteri
- Cerebral metastasis

- Uncontrolled severe infections
- Patients with Kaposi's sarcoma
- Peripheral neuropathy exceeding grade 2 on Common Terminology Criteria for Adverse Events (CTCAE) v5.0
- Previous treatment with taxane
- Patients with known allergy or severe hypersensitivity to any trial drug or drug excipient
- Patients with any other disease or illness which requires hospitalisation or is incompatible with the trial treatment
- Patients unable to comply with trial obligations for geographic, social or physical reasons, or who are unable to understand the purpose and procedures of the trial
- Participation in another clinical trial within 14 days prior to randomization
- Patients deprived of liberty or under legal protection measures or patients whose willingness to participate in the trial may be unduly influenced

Informations promoteur

Nom du promoteur : UNICANCER

Type de promoteur : Institutionnel

Adresse : - 75001 PARIS 01

Coordonnateur : - *Mail :* - *Tél :*

Informations centre investigateur n°1

Nom du centre : CHU de Rouen

Adresse : 1 Rue de Germont 76000 ROUEN

Investigateur : Pr Pierre MICHEL

TEC / ARC / IDE : Patricia FOSSE - *Mail :* patricia.fosse@chu-rouen.fr - *Tél :*

Statut de l'essai : OUVERT

Liens utiles

ClinicalTrials : https://clinicaltrials.gov/ct2/show/NCT03943667?titles=gempax&cntry=FR&rank=1

eCancer : https://www.e-cancer.fr/Professionnels-de-sante/Le-registre-des-essais-cliniques/Le-registre-des-essais-cliniques/Etudes-cliniques/Etude-GEMPAX-etude-de-phase-3-evaluant-l-efficacite-et-la-tolerance-de-la-gemcitabine-associee-a-du-paclitaxel-par-rapport-a-la-gemcitabine-seule-apres-echec-ou-intolerance-a-une-chimiotherapie-de-1re-intention-de-type-FOLFIRINOX-chez-des-patients-aya