DOM-INNATE - (dernière mise à jour : 01/06/2019)

http://archimaid.fr/index.php?action=show&id=401

Informations générales

Titre de l'étude : A Pivotal, Double-Blind, Randomized, Placebo-Controlled, Multinational Study of SGX942 (Dusquetide) for the Treatment of Oral Mucositis in Patients Being Treated With Concomitant Chemoradiation for the Treatment of Squamous Cell Carcinoma of the Head and Neck

Traitement : Radiothérapie

Type d'étude : Hors ciblage moléculaire

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

Schéma : To assess the efficacy of SGX942 compared to placebo in decreasing the duration of severe oral mucositis in patients receiving chemoradiation treatment for the treatment of head and neck cancer.
Patients are randomized 1:1 active/placebo.

Spécialités / Localisations

Spécialité n°1 : Lèvre, cavité buccale et pharynx

CIM10 - Localisation n°1 : **C14** - Tumeur maligne de la lèvre, de la cavité buccale et du pharynx, de sièges autres et mal définis

Critères

Critères d'inclusion : - Biopsy-proven squamous cell carcinoma of the oral cavity or oropharynx without distant organ metastases
- Scheduled to receive cisplatin chemotherapy of 80-100 mg/m²
- Scheduled to receive a continuous course of fractionated, conventional external beam with a cumulative radiation dose between 55 and 72 Gy at each site

Critères de non-inclusion : - Current mucositis
- Current, clinically significant, active infection that in the opinion of the Investigator would make them an unfit participant in the trial
- Planned to receive Erbitux™ (Cetuximab) or similar targeted therapy between Baseline and 6 weeks post-RT
- Prior radiation to the head and neck
- Chemotherapy treatment within the previous 12 months
- Tumors of the lips, sinuses, salivary glands, nasopharynx, hypopharynx, or larynx
- Evidence of significant renal, hepatic, hematologic, or immunologic disease determined by any one of the following: Estimated creatinine clearance <30 mL/min; ALT or AST level greater than 10-fold the upper limit of normal or total bilirubin greater than 3-fold the upper limit of normal; Manifestations of end-stage liver disease, such as ascites or hepatic encephalopathy; Thrombocytopenia; or CD4+ T cell count below 200 cells per ?L
- Evidence of immediate life-threatening disease or a life expectancy of less than 3 months
- Women who are pregnant or breast-feeding
- Participation in any study involving administration of an investigational agent within 30 days of randomization into this study

Informations promoteur

Nom du promoteur : Non renseigné

Type de promoteur :

Adresse : -

Coordonnateur : - *Mail :* - *Tél :*

Informations centre investigateur n°1

Nom du centre : Insititut Andrée DUTREIX

Adresse : 891 avenue de Rosendaël 59240 DUNKERQUE

Investigateur : Docteur Jean-Philippe WAGNER

TEC / ARC / IDE : Florence HENNETIER - *Mail :* fhennetier@iadonco.org - *Tél :* 03 28 51 96 30

Ouverture de l'essai : OUVERT

Liens utiles

ClinicalTrials.gov (anglais) : https://clinicaltrials.gov/ct2/show/NCT03237325