OMET - (dernière mise à jour : 06/08/2019)

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Informations générales

Titre de l'étude : Etude de phase II randomisée multicentrique de traitement systémique et radiothérapie stéréotaxique ablative versus radiothérapie stéréotaxique ablative seule pour le traitement d'oligométastases de cancers épidermoïdes des voies aérodigestives supérieures

Traitement : Métastasique ou localement avancé / Radiothérapie

Type d'étude : Hors ciblage moléculaire

Phase : II **Stade** : Métastatique **Ligne(s)** : 1

Schéma : The aim of this study is to evaluate the rate of living patients at 1 year with a quality of life criteria (no decrease) and reduced toxicities. This criteria will be compared in both groups., A cost effectiveness study is scheduled also.

2 arms:
- Active Comparator: Chemotherapy combined with stereotactic radiotherapy (RT)
Chemotherapy is based on patient Performance Status (PS) and comorbidities:
-> PS 0-1: standard treatment: 6 cycles, every 3 weeks cisplatin (100 mg/m² iv on D1), 5FU (4000 mg/m² total dose starting on Day 1 to Day 4 and during 96h in continuous infusion)
-> PS 2/cardiac contra-indication to 5 Fluorouracil (5FU): 6 cycles, every 3-4 weeks cisplatin (100 mg/m² iv on Day 1) or carboplatin Area Under Curve (AUC) 4 or 5 on Day 1 In both case: Cetuximab (loading dose 400 mg/m² iv on Day1, then 250 mg/m² weekly or 500mg/m² every 2 weeks).
Cycle 1 of systemic treatment will be administered before the start of the stereotactic RT. Then, following cycles will be performed after the end of stereotactic irradiation.
Cetuximab maintenance: 250 mg/m² iv weekly. It will be given only if at least disease stabilization is observed at the end of chemotherapy, and will be continued until progression or unacceptable toxicity.

- Experimental: stereotactic radiotherapy
Splitting will be based on the tumor diameter, and proximity of organs at risk which constitutes any limiting toxicities. It will be 3 or 5 fractions based on the recommendations (CARO-Stereotactic Body Radiation Therapy (SBRT) 2012) and for the purpose of harmonization practices. The prescription dose is 3 x 10 = 30 Gy 3 x 11 = 33 Gy or 3 x 15 = 45 Gy (if 3 fractions) with the possibility of 3 x 20 Gy to the peripheral lung nodules with tracking in Cyberknife or 5 x 7 = 35 Gy or 5 Gy x 10 = 50 (if 5 fractions). Beyond 3 cm of tumor diameter and / or to a distance of less than 1 cm from the GTV in an organ critical risk (eg spinal cord), a splitting up into 5 sessions must be privileged.

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

Spécialité n°2 : Organes respiratoires et intrathoraciques

CIM10 - Localisation n°2 : **C30** - Tumeur maligne des fosses nasales et de l'oreille moyenne

Spécialité n°3 : Organes respiratoires et intrathoraciques

CIM10 - Localisation n°3 : **C31** - Tumeur maligne des sinus de la face

Spécialité n°4 : Organes respiratoires et intrathoraciques

CIM10 - Localisation n°4 : **C32** - Tumeur maligne du larynx

Critères

Critères d'inclusion : - Age >= 18 years
- PS:0-2
- Estimated life expectancy >= 6 months
- Histologically confirmed diagnosis of squamous cell carcinoma of the head and neck
- Target metastases can be treated in stereotactic radiotherapy
- 1-3 synchronized metastases with unrestricted anatomic site
- Greater cumulative diameter of synchronous metastases in once organ (liver, lung or brain) <= 6 cm with GTV = Clinical Target Volume (CTV)
- Global maximum diameter (GTV) allowed for pulmonary oligometastases (less than 2 cm from the mediastinum), brain, node, is <= 3cm
- Implementation of a method for taking into account movements and uncertainties (IGRT) for limiting the margin of CTV to PTV (PTV) so as not to exceed 7 cm large cumulative diameter of PTV
- Performing a positron emission tomography with 18F-2-fluoro-2-deoxy-D-glucose (FDG-PET) 4 weeks before the inclusion
- In case of cerebral metastases, MRI diagnostic is required
- If locoregional disease is treated, controlled and non-progressive for more than three months (+/- 4 weeks) at baseline, synchronized initial tumor is possible
- If metachronous metastases, locoregional disease previously treated should be monitored and considered not progressive for more than three months at baseline
- In case of prior cancer other than HNSCC, complete remission for over 5 years is possible, any biopsy of metastases is left to the appreciation of referring physician
- No chemotherapy or local treatment of metastases in the previous 6 months
- Laboratory tests consistent with the achievement of chemotherapy: Leukocytes> 3,000 / mm3 (including polynuclear> 2000 / mm3) platelets> 150,000 / mm3, serum glutamate oxaloacetate transminase (SGOT), serum glutamate pyruvate transaminase (SGPT), alkaline phosphatase, bilirubin <2.5 upper limit of normal (ULN)
- Affiliation to an health insurance
- Informed Consent Form signed

Critères de non-inclusion : - Concomitant participation in other interventional clinical trial within 4 weeks before inclusion
- Other prior ablative treatment of targets metastases (surgery, radio frequency) in the previous six months
- Metachronous primitive tumor (second cancer) uncontrolled.
- Contraindication to any systemic therapy (chemotherapy and / or targeted therapy)
- Known hypersensitivity reaction to 5FU, cisplatin, carboplatin, platin or cetuximab
- Active infection (infection requiring IV antibiotics), including active tuberculosis and known and declared human immunodeficiency virus (HIV)
- Other malignancies within 5 years prior to randomization, with the exception of adequately treated basal skin cancer and carcinoma in situ of the cervix
- Individual deprived of liberty by judicial or administrative decision, or under any kind of guardianship
- Pregnant or breast feeding women. Every woman who has childbearing potential, must have a negative pregnancy test (serum or urine) within 14 days previous treatment. Patients (men or women) must use a reliable method of contraception throughout treatment and for at least 6 months after discontinuation of chemotherapy.

Informations promoteur

Nom du promoteur : Groupe Oncologie Radiothérapie Tête et Cou (GORTEC)

Type de promoteur : Institutionnel

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Coordonnateur : - *Mail :* - *Tél :*

Informations centre investigateur n°1

Nom du centre : Centre François BACLESSE

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Ouverture de l'essai : OUVERT

Liens utiles

ClinicalTrials : https://clinicaltrials.gov/ct2/show/NCT03070366?titles=omet&cntry=FR&rank=1