VESPER - (dernière mise à jour : 26/09/2017)

https://archimaid.fr/index.php?action=show&id=42

Informations générales

Titre de l'étude : Etude de phase III randomisée, comparant l'efficacité de l'association Gemcitabine et Cisplatine (GC) versus l'association Methotrexate, Vinblastine, Doxorubicine et Cisplatine à haute dose (MVAC–HD) dans le traitement péri–opératoire de patients présentant un carcinome à cellules transitionnelles (CCT) de vessie infiltrant le muscle

Traitement : Adjuvant

Type d'étude : Hors ciblage moléculaire

Phase : III **Stade** : NA **Ligne(s)** : 1

Schéma : Randomized Phase III Study of Gemcitabine/Cisplatine (GC) Versus High-dose Intensity Methotrexate, Vinblastine, Doxorubicine and Cisplatin (HD-MVAC) in the Perioperative Setting for Patients With Locally Advanced Transitional Cell Cancer of the Bladder

2 arms:
- Experimental: GC
gemcitabine 1250 mg/m2 D1 and D8 cisplatine 70 mg/m2 D1 each cycle every 3 weeks, 4 cycles
- Active Comparator: MVAC-HD
Methotrexate 30 mg/m2 D1 Vinblastine 3 mg/m2 D2 Doxorubicine 30 mg/m2 D2 Cisplatine 70 mg/m2 D2 G-CSF D3 and D9
Each cycle every 2 weeks, 6 cycles

Spécialités / Localisations

Spécialité n°1 : Voies urinaires

CIM10 - Localisation n°1 : **C67** - Tumeur maligne de la vessie

Critères

Critères d'inclusion : - Primary tumour of the bladder
- Histologically confirmed infiltrating urothelial carcinoma (epidermoid and/or glandular variants are accepted if combined with TCC)
- Disease defined by a T2, T3 or T4a N0 (lymph node £ 10 mm on CT scan) M0 stadification for patients receiving neoadjuvant chemotherapy OR pT3 or pT4 OR pN+ whatever pT and M0 for patients receiving adjuvant chemotherapy
- 18 <= age <= 80 years
- General condition 0 or 1 as per the WHO scale
- Absence of previous chemotherapy for muscle-invasive disease
- Haematological function: Haemoglobin > 11 g/dl, neutrophils >= 1500/mm3, platelets >= 100,000/mm3
- Liver function: Grade* 0 ASAT and ALAT, grade* 0 alkaline phosphatases, normal bilirubin
- Renal function: calculated (or measured) creatinine clearance ³ 40 ml/min
- Patients covered by a social security scheme
- Patient having read the information sheet and signed the informed consent form.

Critères de non-inclusion : - Pure adenocarcinoma or pure epidermoid carcinoma or mixed or pure small-cell neuroendocrine carcinoma

- Ventricular ejection fraction < 50%
- History of cancer in the 5 years prior to entry in the trial other than basal cell skin cancer or in situ epithelioma of the cervix
- Male or female patients not agreeing to use an effective method of contraception throughout the duration of treatment and for 6 months after treatment discontinuation
- Pregnant women, or female subjects liable to become pregnant or currently breast-feeding,
- Patient already included in another therapeutic trial on an investigational medicinal product,
- Persons deprived of their freedom or under judicial protection (including guardianship)
- Unable to receive medical follow-up during the trial owing to geographical, social or psychological reasons.

Informations promoteur

Nom du promoteur : CHU de Rouen

Type de promoteur : Institutionnel

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Informations centre investigateur n°1

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Ouverture de l'essai : CLOS

Liens utiles

Clinicaltrials : https://clinicaltrials.gov/ct2/show/NCT01812369?titles=vesper&cntry1=EU%3AFR&rank=1

INCa : http://www.e-cancer.fr/Professionnels-de-sante/Le-registre-des-essais-cliniques/Le-registre-des-essais-cliniques/Etudes-cliniques/Etude-VESPER-etude-de-phase-3-randomisee-comparant-l-efficacite-d-une-chimiotherapie-peri-operatoire-associant-de-la-gemcitabine-et-du-cisplatine-GC-par-rapport-a-une-chimiotherapie-peri-operatoire-associant-du-methotrexate-de-la-vinblastine-de-la