CHIPPI - CHIPPI-1808 (dernière mise à jour : 30/04/2019)

https://archimaid.fr/index.php?action=show&id=487

Informations générales

Titre de l'étude : Etude randomisée de phase III évaluant la Chimiothérapie Hyperthermique Intra-Péritonéale (CHIP) au cours d'une chirurgie première ou intervallaire dans le traitement du cancer de l'ovaire

Traitement : Métastasique ou localement avancé / Chirurgie

Type d'étude : Hors ciblage moléculaire

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

Schéma : L'objectif de la recherche est de déterminer si l'ajout d'une chimiothérapie hyperthermique intrapéritonéale (CHIP) à l'issue de la chirurgie a un effet sur la survie des patientes.

La CHIP consiste à réaliser au bloc opératoire, à la fin de la chirurgie, une fois que la plus grande partie ou la totalité du cancer a été enlevée, un bain de chimiothérapie dans la cavité intra-péritonéale à une température de 40 degrés pendant 1h30. Cette CHIP a pour but de tuer les cellules circulantes cancéreuses encore présentes dans la cavité intra-péritonéale ou de détruire les nodules cancéreux persistants de moins de 2.5 mm de diamètre.

The primary objective of this study is to assess the efficacy, in terms of disease-free survival (DFS), the use of HIPEC treatment combined with standard care (PDS or IDS) or standard care alone (PDS or IDS alone).

Secondary objectives of the study include:
- Evaluating the efficacy of HIPEC in terms of overall survival (OS) in combination with standard of care
- Evaluating the morbidity associated with HIPEC.
- Evaluating the trade-off between efficacy and morbidity using the Q-TWiST approach.
- Evaluating the impact of HIPEC in terms of quality of life.

Exploratory objectives (optional) include:
- Evaluating the impact of HIPEC on the count of residual viable cells (evaluated by flow cytometry) in abdominal drainage fluids for patients recruited in Centre Oscar Lambret only.
- Constituting a biobank (tumoral samples and blood samples) for future translational researches

Spécialités / Localisations

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

CIM10 - Localisation n°1 : **C56** - Tumeur maligne de l'ovaire

Spécialité n°2 : Seins, organes génitaux de la femme

CIM10 - Localisation n°2 : **C57** - Tumeur maligne des organes génitaux de la femme, autres et non précisés

Critères

Critères d'inclusion : Pre-eligibility criteria to be checked before surgery for preregistration

- Age >=18 years 1. and <= 76 years
- Histologically proven primary epithelial ovarian carcinoma or fallopian tube carcinoma or peritoneal carcinoma (including serous papillary adenocarcinoma, clear-cell carcinoma, mucinous adenocarcinoma and endometrioid carcinoma)
2. FIGO (International Federation of Gynecology and Obstetrics) stage III
3. Patient eligible for
- Primary Debulking Surgery (PDS) with planned adjuvant chemotherapy +/- bevacizumab or other targeted therapy
- Or Interval Debulking Surgery (IDS) after neoadjuvant chemotherapy +/- bevacizumab or other targeted therapy, with or without planned adjuvant
chemotherapy +/- bevacizumab or other targeted therapy. In case of neo-adjuvant chemotherapy, surgery should be performed in a time interval of 3 to
5 weeks in case of chemotherapy without bevacizumab, and in a time interval of 4 to 6 weeks if chemotherapy is combined with bevacizumab. The
patient remains eligible for the study if surgery is delayed beyond the recommended time interval.
- WHO (World Health Organization Performance Status) <= 2
6. Physical status score ASA (American Society of Anesthesiologists) <= 2
7.Adequate bone marrow and renal function, as evidenced by the following tests performed within 7 days prior to surgery:
Absolute Neutrophil Count (ANC) >=1,500/mm3
Platelets >=100,000/mm3
Aspartate aminotransferase (ALT)/ Alanine
aminotransferase (ALT) <=2.5 × upper limit of normal
(ULN) (<=5.0 × ULN in case of liver metastases)
Total bilirubin <=1.5 × ULN (except in case of Gilbert's disease)
Creatinine clearance >= 60 mL/ min
8. Negative serum pregnancy test within 7 days prior to surgery for women of childbearing potential. For nonmenopausal women, if no hysterectomy is planned, willing to accept the use of an effective contraceptive regimen
during the treatment period and at least 6 months after the end of treatment (surgery or adjuvant chemotherapy)
9.Absence of contraindication to receive the products used in this study (cisplatin and products used in neo-adjuvant/adjuvant chemotherapy) according to the most recent SmPC (Summary of Product Characteristics) of these products
10. Patient is willing and able to comply with the protocol for the duration of the study including undergoing treatment and scheduled visits and examinations including follow-up
11. Signed written 11. informed consent
12. Patient covered by the French or Belgian "Social Security" regime Criteria to be checked per-operatively for confirmation of enrolment and randomization
13. Residual disease after surgery (cytoreduction score CC) CC-0 (no macroscopic residue) or CC-1 (residue < 2.5 mm)
14. Per-operative hemorrhage < 2.5 L
15. Strictly less than 3 digestive resections performed during surgery
16. Diuresis during surgery >= 1 mL/ kg/ h

Critères de non-inclusion : 1. Benign disease, borderline disease, non epithelial ovarian
carcinoma or carcinosarcoma
2. Cirrhosis
3. Known hypersensitivity to any of the study drugs, study drug classes, or excipients in the formulation
4. Auditory impairment
5. Dehydration or intercurrent disease that contraindicates hyperhydration (including cardio-respiratory disease)
6. Other uncontrolled intercurrent disease including, but not limited to: diabetes; hypertension; symptomatic congestive heart or pulmonary failure; renal, hepatic or severe gastrointestinal (associated with diarrhea) chronic disease
7. Any unresolved NCI-CTCAE Grade >= 2 toxicity from
previous anticancer therapy
8. Concomitant treatment with prophylactic phenytoin
9. Receipt of live attenuated vaccine, including yellow fever vaccine, within 30 days prior to inclusion (and, if patient is enrolled, up to 30 days after the last administration of study treatment)
10. Pregnant or breastfeeding woman
11. Psychiatric illness or social situation that would limit compliance with study requirement, substantially increase the risk of side effects, or compromise the ability of the patient to give written informed consent
12. Inability to comply with medical follow-up of the trial
(geographical, social or psychic reasons)
13. Person under guardianship

Informations promoteur

Nom du promoteur : Centre Oscar Lambret

Type de promoteur : Institutionnel

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Coordonnateur : Docteur Fabrice NARDUCCI - *Mail :* - *Tél :*

Informations centre investigateur n°1

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Ouverture de l'essai : OUVERT

Liens utiles

Centre Oscar Lambret : https://www.centreoscarlambret.fr/recherche-cancerologique/essais-cliniques/protocole-chippi

ClinicalTrials.gov (anglais) : https://clinicaltrials.gov/ct2/show/NCT03842982