TOMMY - ICO-2012-04 (dernière mise à jour : 13/02/2020)

http://archimaid.fr/index.php?action=show&id=818

Informations générales

Titre de l'étude : Phase 1-2 Study of the Combination of Escalated Total Bone Marrow Irradiation (TBMI) by Helicoidal Tomotherapy and a Fixed High-dose Melphalan (140 mg/m²) Followed by Peripheral Stem Cell Rescue (PSC) in First Relapsed Multiple Myeloma.

Traitement : Radiothérapie

Type d'étude : Hors ciblage moléculaire

Phase : I/II **Stade** : NA **Ligne(s)** :

Schéma : Experimental :

Total Bone Marrow Irradiation (TBMI) is delivered by the Tomotherapy HI-ART machine, in 2 fractions per day during 4 consecutive days from d -6 to d -3. The escalated dose levels are determined according to a "3x3" modified Fibonacci method and five dose levels will be explored. The doses per fraction are: 1gy, 1.25gy, 1.5gy, 1.75gy and 2gy, and consequently the cumulative TBMI doses are: 8gy, 10gy, 12gy, 14gy and 16gy.

Drug : Melphalan is infused intravenously in 30 minutes on day -2 after IV anti-emetics.

Autologous Peripheral Stem Cell Rescue : are re-infused in the central line on day "0" after adequate premedication.

Despite the recent finding of new drugs (proteasome inhibitors and IMIDs), Multiple Myeloma still remain uncurable, especially after the first relapse, even in responding disease under conventional chemotherapy. In the healthy youngest patients (<65 yo), when peripheral stem cells collection is available, a high-dose therapy is often proposed in consolidation of complete or very good partial remission: the conditioning regimen usually includes high dose alkylating agent (mostly Melphalan) and/or Total Body Irradiation. The new Tomotherapy HI-ART technology allows irradiating on a 1.6m length field all the bone marrow sites together with optimal respect of the Organ at Risk (lungs, oral cavity, heart, liver, kidneys…). The proposed phase-1 study will explore the safety and efficacy of escalated dose of Total Bone-Marrow Irradiation in combination with a fixed dose of Melphalan (140mg/m²), followed by autologous SCR. To determine the MTD is the main objective of the study, then the toxicity profile (DLTs) and the RP2D in an extended cohort at the MTD dose.

Current primary outcome:
Maximal Tolerated Dose, type of Dose-Limiting Toxicities [Time Frame: 1 year]

Current secondary outcomes:
- Safety profile Recommended Dose for Phase-2 (RDP2) [Time Frame: 1 year]
Safety profile: acute, short and middle term toxicities Recommended Dose for Phase-2 (RDP2) and Extended Cohort for 14 patients at this dose
- Efficacy [Time Frame: 1 and 2 years]
Bone-marrow control evaluation by FDG PET-Scan Disease-free survival at 1 year and Overall Survival

Spécialités / Localisations

Spécialité n°1 : Tissus lymphoïde, hématopoïétique et apparentés

CIM10 - Localisation n°1 : **C90** - Myélome multiple et tumeurs malignes à plasmocytes

Critères

Critères d'inclusion : - Multiple Myeloma in first relapse.
- In Complete or very good partial remission
- Available Collected Autologous Peripheral Stem cells: 2.5x106 CD34+/Kg

Critères de non-inclusion : - Uncontrolled visceral disease: kidney, heart, lung, diabetes mellitus
- Previous Total body irradiation
- Any previous radiation dose to the spinal cord which could reach to 45gy equivalent, including the proposed TBMI
- Amyloidosis
- Brain localizations

Informations promoteur

Nom du promoteur : INSTITUT DE CANCEROLOGIE DE L'OUEST

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Ouverture de l'essai : CLOS

Liens utiles

ClinicalTrials (anglais) : https://clinicaltrials.gov/ct2/show/record/NCT01794572?term=NCT01794572&rank=1&view=record