Essai Clinique

Généré le 26 avr. 2025 à partir de

Titre	LCH-IV, Protocole de traitement collaboratif international pour enfants et adolescents atteints d'histiocytose à cellules de Langerhans
Protocole ID	LCH-IV
ClinicalTrials.gov ID	NCT02205762
Type(s) de cancer	Pédiatrique divers
Phase	Phase II
Type étude	Traitement
Institution	CENTRE HOSPITALIER UNIVERSITAIRE SAINTE-JUSTINE
Ville	Montréal
Investigateur principal	Dr Jean-Marie Leclerc
Coordonnateur	Maud Frizot 514-345-4931 poste 5467
Statut	Actif en recrutement
But étude	The LCH-IV is an international, multicenter, prospective clinical study for pediatric Langerhans Cell Histiocytosis LCH (age < 18 years).

Critères d'éligibilité	• Stratum I
	  • Patients must be less than 18 years of age at the time of diagnosis.
	  • Patients must have histological verification of the diagnosis of Langerhans cell histiocytosis according to the criteria described in Section 6.1
	  • Signed informed consent form
	• Stratum II
	  • Patients of Stratum I who have:
	  • Progressive disease (AD worse) in non-risk organs after 6 weeks (Initial Course
	  • AD intermediate or worse in non-risk organs or AD better in risk organs after 12 weeks (Initial Course 2)
	  • Disease progression (AD worse) in non-risk organs at any time during continuation treatment
	  • Active disease at the end of Stratum I treatment
	  • Disease reactivation in non-risk organs at any time after completion of Stratum I treatment
	• Stratum III
	  • Patients from Stratum I who fulfill the following criteria:
	  • AD worse in risk organs after week 6 (after Initial Course 1), or AD worse or AD intermediate in risk organs after week 12 (after Initial Course 2).
	  • Presence of unequivocally severe organ dysfunction at the above mentioned evaluation points (hematological dysfunction, liver dysfunction, or both of them) as
	  • Hb <70 g/L (<7.0 g/dl) and/or transfusion dependency
	  • PLT <20 x109/L (20,000/µL) and/or transfusion dependency (both criteria have to be fulfilled) AND/OR
	  • Liver dysfunction (or digestive involvement with protein loss)
	  • Total protein <55 g/L or substitution dependency
	  • Albumin <25 g/L or substitution dependency (at least one of the two criteria to be fulfilled)
	• Stratum IV
	  • Patients from Stratum I or Stratum III who fulfill the following criteria:
	  • AD worse in risk organs after week 6 (after Initial Course 1), or AD worse or AD intermediate in risk organs after week 12 (after Initial Course 2) of Stratum I OR
	  • AD worse after the 2nd and 3rd 2-CdA/Ara-C course, and those AD worse or AD intermediate after the 4th 2-CdA/Ara-C course of Stratum III AND

	• Presence of unequivocally severe organ dysfunction at the above mentioned evaluation points (hematological dysfunction, liver dysfunction, or both of them) as defined in Table XI (see Section 10.3.1). • Informed consent: All patients or their legal guardians (if the patient is <18 years of age) must sign an Ethics or institutional Review Board approved consent form indicating their awareness of the investigational nature and the risks of this study. When appropriate, younger patients will be included in all discussions in order to obtain assent. • Adequate organ function: Patients should have adequate hepatic, renal, cardiac and pulmonary function to undergo reduced intensity HCT based upon local institutional guidelines, or at a minimum meet requirements noted in eligibility checklist Appendix A-VIII_1. However, significant hepatic and pulmonary dysfunction, if secondary to underlying LCH disease activity, will not exclude patients from protocol enrollment and should be discussed with the National PI Coordinator and the Coordinating Principal Investigator. • Stratum V • All patients with verified diagnosis of LCH and MRI findings consistent with ND-CNSLCH irrespective of previous treatments (also those not registered to other Strata ofLCH-IV). • Patients with isolated tumorous CNS-LCH (including isolated DI with mass lesion in the hypothalamus-pituitary axis). In patients with already established diagnosis of LCH and radiologic finding of CNS lesions compatible with LCH, a biopsy of the lesion is not obligatory. In all other cases a biopsy of the lesion is needed for inclusion into the study • Stratum VI : Patients with newly diagnosed SS-LCH and localization other than "multifocal bone",isolated tumorous CNS lesion, or isolated "CNS-risk" lesion. • Stratum VII : All patients registered in LCH IV (regardless of treatment) as long as consent for longterm follow-up has not been withheld.
Critères d'exclusion	• Stratum I • Pregnancy (patients of child-bearing age must be appropriately tested before chemotherapy) • LCH-related permanent consequences (e.g. vertebra plana, sclerosing cholangitis, lung fibrosis, etc.) in the absence of active disease • Prior systemic therapy • Stratum II • Patients with progressive disease in risk organs • Permanent consequences (e.g. sclerosing cholangitis, lung fibrosis, etc.) without evidence of active LCH in the same organ or in any other locations • No written consent of the patient or his/her parents or legal guardian • Stratum III • The presence of any of the following criteria will exclude the patient from the study: • Isolated sclerosing cholangitis without evidence of active hepatic LCH as the only evidence of risk organ involvement. • Inadequate renal function as defined by serum creatinine > 3x normal for age • Stratum IV • Pulmonary failure (requiring mechanical ventilation) not due to active LCH. • Isolated liver sclerosis or pulmonary fibrosis, without active LCH. • Uncontrolled active life-threatening infection. • Decreased renal function with a GFR of less than 50ml/1.73m2/min. • Pregnancy or active breast feeding • Failure to provide signed informed consent • Stratum VI • Patients with SS-LCH who have an isolated tumorous CNS lesion (they are eligible for Stratum V), • Patients with isolated "CNS-risk" or multifocal bone lesions (they are eligible for Stratum I, Group 2)