

ENSAYOS CLÍNICOS HEMATO-ONCOLOGÍA PEDIÁTRICA HOSPITAL UNIVERSITARIO LA PAZ

ESTUDIO	CÓDIGO/ IP	FASE	TTO EN INVESTIGACIÓN	SITUACIÓN	PROTOCOLO VIGENTE
LEUCEMIAS/ LINFOMAS					
International cooperative treatment protocol for children and adolescents with lymphoblastic lymphoma (LBL 2018)	EudraCT number: 2017-001691-39 IP: Berta González Académico	3	Primera línea	Activo	
LCH-IV International Collaborative Treatment Protocol for Children and Adolescents with LANGERHANS CELL HISTIOCYTOSIS	EudraCT Nr.: 2011-001699-20 IP: Antonio Pérez Académico	3	Primera línea	Activo	
TUMORES SÓLIDOS					
UMBRELLA Protocol SIOP-RTSG 2016 - Integrated research and guidelines for standardized diagnostics and therapy of kidney tumours in children, adolescents and young adults	2016-004180-39 IP: Pedro Rubio Académico	3	Primera línea	Activo	VERSION 2.0 Oktober 2018
PHITT: Paediatric Hepatic International Tumour Trial	2016-002828-85 IP: Diego Plaza Académico	3	Primera línea	Activo	Version 3.0 17th October 2018
LINES: European Low and Intermediate Risk Neuroblastoma Protocol (Phase III)	EudraCT number: 2010-021396-81 IP: Pedro Rubio	3	Primera línea	Activo	Version 7.0 5 July 2019
An international clinical program for the diagnosis and treatment of children, adolescents and young adults with ependymoma (ET-13-002) SIOP Ependymoma II	EudraCT Number: 2013-002766-39 IP: Diego Plaza	3	Primera línea	Activo	FINAL Protocol Version 3.0 January 17th, 2017
An overarching study for children and adults with Frontline and Relapsed RhabdoMyoSarcoma	EudraCT Number: 2018-000515-24 IP: Pedro Rubio	3	Primera línea/Recaidas	Activo	Protocol Version 1.0a 7th March 2019
TPH					
A Phase 3, Open-label, Single Arm, Multicenter Study of Ravulizumab in Addition to Best Supportive Care in Pediatric Participants (from 1 month to < 18 years of age) with Thrombotic Microangiopathy (TMA) after Hematopoietic Stem Cell Transplantation	EudraCT number: 2020-000761-16 IP: David Bueno	3	Ravulizumab	Activo	25 Mar 2020

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(HSCT): ALXN1210-TMA-314	Alexion Pharmaceuticals, Inc.				
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ENSAYOS CLÍNICOS FASES PRECOCES (I/II)

ESTUDIO	CÓDIGO/ IP	FASE	TTO EN INVESTIGACIÓN	SITUACIÓN	PROTOCOLO VIGENTE
LEUCEMIAS/ LINFOMAS					
Long Term Follow-Up of Patients Exposed to Lentiviral- Based CAR T-Cell Therapy	CCTL019A2205B IP: Berta González Novartis	Follow-up	TISAGENLECLEUCEL	Activo	Amended Protocol Version No. 03 released on 12-Jul-2019
A phase 2, single arm, multicenter, open label trial to determine the safety and efficacy of tisagenlecleucel in pediatric patients with relapsed or refractory mature B cell non-Hodgking lymphoma	CCTL019C2202 (BIANCA) IP: Berta González Novartis	2	TISAGENLECLEUCEL	Activo- ya no recluta	Clinical Trial Protocol Template Version 1.0 (01-Dec-2017). Release date: 14 Jan 2020
A Phase 1/2, Multi-Center, Dose-Escalating Study To Evaluate The Safety, Pharmacokinetics, Pharmacodynamics, And Efficacy Of Quizartinib Administered In Combination With Re-Induction Chemotherapy, And As A Single-Agent Maintenance Therapy, In Pediatric Relapsed/Refractory AML Subjects Aged 1 Month To < 18 Years (And Young Adults Aged Up To 21 Years) With FLT3-ItD Mutations	AC220-A-U202 IP: Antonio Pérez-Martínez Daiichi Sankyo, Inc.	1/2	QUIZARTINIB	Activo	VERSION 1.0, 20 DECEMBER 2017 (Amendment 19 APR 2018)
Phase 1b/2 Study of Carfilzomib in Combination With Induction Chemotherapy in Children With Relapsed or Refractory Acute Lymphoblastic Leukemia	20140106 IP: Berta González	1b/2	CARFILZOMIB	Activo	Amendment 9/ 04 February 2021
A Phase 1/2 Multi-Center Study Evaluating the Safety and Efficacy of KTE-X19 in Pediatric and Adolescent Subjects with Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia or Relapsed/Refractory B-Cell Non-Hodgkin Lymphoma (ZUMA-4)	ZUMA 4 IP: Antonio Pérez-Martínez EudraCT Number: 2015-005010-30	1/2	Terapia celular CAR-T	Activo	Amendment #6 13 MARCH 2020
TUMORES SÓLIDOS					
An open-label, uncontrolled, multicenter phase II trial of MK-3475 (Pembrolizumab) in Children and Young Adults with newly diagnosed Classical Hodgkin Lymphoma with inadequate (slow	MK3475-667 IP: Diego Plaza	2	PEMBROLIZUMAB	Activo	Protocol/Amendment No.: 667-03

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early) Response to Frontline Chemotherapy (KEYNOTE 667	Merck				
A Phase 1/2 single-arm study evaluating the safety and efficacy of eribulin mesilate in combination with irinotecan in children with refractory or recurrent solid tumors	E7389-G000-213 IP: Ana Sastre Eisai	1/2	ERIBULINA	Cerrado en Sept 2021	Amendment 01 10 May 2018
A Phase I, Open-label, Parallel Group Study to Investigate Olaparib Safety and Tolerability, Efficacy and Pharmacokinetics in Paediatric Patients (aged 6 months to 17 years) with Solid Tumour	D0816C00025 (LYNPARZA) IP: Pedro Rubio Astra Zeneca	1	OLAPARIB	Activo	3.0 18 May 2020
A Multicenter, Open-label, Randomized Phase 2 Study to Compare the Efficacy and Safety of Lenvatinib in Combination with Ifosfamide and Etoposide versus Ifosfamide and Etoposide in Children, Adolescents and Young Adults with Relapsed or Refractory Osteosarcoma (OLIE)	E7080-G000-230 IP: Ana Sastre Eisai	2	LENVATINIB	Activo	FINAL: 08 Oct 2019
International randomised controlled trial of chemotherapy for the treatment of recurrent and primary refractory Ewing sarcoma (rEECur)	2014-000259-99 IP: Pedro Rubio Académico CRCTU	2	Distintas combinaciones de QT	Activo	
CAMPFIRE: A Study of Ramucirumab (LY3009806) in Children and Young Adults With Desmoplastic Small Round Cell Tumor (JS1-MC-JV01)	NCT04145349 IP: Pedro Rubio Eli Lilly	1/2	Ramucirumab	Activo	Protocol Addendum Amendment JV01(d)
CAMPFIRE: A Study of Ramucirumab (LY3009806) in Children and Young Adults With Synovial Sarcoma	NCT04145700 IP: Pedro Rubio Eli Lilly	1/2	Ramucirumab	Activo	Protocol Addendum Amendment JV02(f)
A PHASE 1, MULTICENTRE, OPEN-LABEL, DOSE-ESCALATION AND COHORT EXPANSION STUDY OF NIRAPARIB AND DOSTARLIMAB IN PAEDIATRIC PATIENTS WITH RECURRENT OR REFRACTORY SOLID TUMOURS	EudraCT Number: 2020- 002359-39 IP: Pilar Guerra GSK	1	Niraparib Dostarlimab	Activo	1.1 (version 1.0 never implemented)
Phase II trial of sunitinib plus nivolumab after standard treatment in advanced soft tissue and bone sarcomas	EudraCT Number: 2016- 004040-10 IP: Pedro Rubio	2	SUNITINIB + NIVOLUMAB	Activo	5 of 12 June 2019

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Tumor-agnostic precision immuno-oncology and somatic targeting rational for you (tapistry) phase ii platform trial (TAPISTRY)	IP: Javier de Castro	2		Activo	
TPH					
A Phase I/II open-label, single-arm, multi-center study of ruxolitinib added to corticosteroids in pediatric patients with grade II-IV acute graft vs. host disease after allogeneic hematopoietic stem cell transplantation	CINC424F12201 (REACH 4) IP: Yasmina Mozo	1/2	RUXOLITINIB	Activo- ya no recluta	01-Apr-2019
A phase 2 open-label, single-arm, multi-center study of ruxolitinib added to corticosteroids in pediatric subjects with moderate and severe chronic graft vs. Host disease after allogeneic stem cell transplantation	CINC424G12201 (REACH 5) IP: Yasmina Mozo	2	RUXOLITINIB	Activo	08-Apr-2019
A Phase 2b open-label, single-arm study to evaluate pharmacokinetics, efficacy, safety and tolerability of letermovir in pediatric participants from birth to less than 18 years of age at risk of developing CMV infection and/or disease following allogeneic haematopoietic stem cell transplantation (HSCT)	MK8228-030 IP: Antonio Perez-Martínez Merck	2b	LETERMOVIR	Activo	030-00
Phase 1/2 Dose Finding, Safety and Efficacy Study of Ibrutinib in Pediatric Subjects with Chronic Graft Versus Host Disease (cGVHD)	PCYC-1146-IM IP: Luisa Sisinni	1/2	IBRUTINIB	Activo	17 September 2018
Evaluation of safety, feasibility and preliminary efficacy of MSCs from third party donors in the treatment of patients with osteonecrosis of the femoral head after allogeneic stem cell transplantation (AloFem)	AloFem IP: Enrique Gómez Barrena Académico (FIBHULP)	2a	Terapia celular	Activo	V2.0 Date: 2020-08-06
Ensayo Clínico aleatorizado y multicéntrico para evaluar la efectividad y la eficiencia de una estrategia de genotipado anticipado de voriconazol en pacientes con riesgo de aspergilosis	VORGENIPHARM IP: Alberto Borobia FIBHULP		-	Activo	
Infusión de células Natural Killer aloreactivas o estimuladas con IL-15 <i>ex vivo</i> tras trasplante haploidéntico de progenitores hematopoyéticos en pacientes pediátricos con neoplasias hematológicas (PHINK)	EduraCT: 2019-000911-10 IP: Antonio Martínez Académico: FIBHULP	1/2	Terapia celular	Activo	2.0 de 24 de junio de 2020
OTROS					
	RELEASE	1/2	Terapia celular	Activo	

ENSAYOS CLÍNICOS HEMATO-ONCOLOGÍA PEDIÁTRICA HOSPITAL UNIVERSITARIO LA PAZ

A phase I/II dose-escalation multi center study to evaluate the safety of infusion of NatuRal KillEr cells or MEMory T cells as Adoptive therapy in coronavirUS pnEumonia and/or lymphopenia	IP: Antonio Pérez Académico				
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OTROS ESTUDIOS ABIERTOS					
International study of chronic myeloid leukemia (CML) treatment and outcomes in children and adolescents.	I-CML-Ped Study IP:				
Guia de recomendaciones de la sehop para el tratamiento de la leucemia linfoblástica aguda o bifenotípica del lactante menor de 1 año	INTERFANT-06 IP: Berta González			Activo	Versión 1.0. Julio 2018
Torque teno virus (TTV) en pacientes sometidos a trasplante alogénico de progenitores hematopoyéticos (TPH) como potencial marcador endógeno de función inmune y complicaciones. Estudio prospectivo.					
Optimización de métodos para la preservacion de la fertilidad masculina en pacientes con cáncer o síndromes genéticos	IP: Antonio Pérez??			Activo	
PRedictive In-silico Multiscale Analytics to support cancer personalized diaGnosis and prognosis, Empowered by imaging biomarkers Business Place	PRIMAGE			Pendiente de comité	

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PENDIENTES:

- An international multicenter phase II randomised trial evaluating and comparing two intensification treatment strategies for metastatic neuroblastoma patients with a poor response to induction chemotherapy A SIOPEN Study (VERITAS). EudraCT N°: 2015-003130-27 (protocol versión V2.0 dated 08th August 2018)
- CAR4SAR

TOTAL:

Hemato: 7 (5 fase I/II, 2 fase III)

Onco: 13 (8, 5)

TPH: 7 (2, 4)

Otros: 3