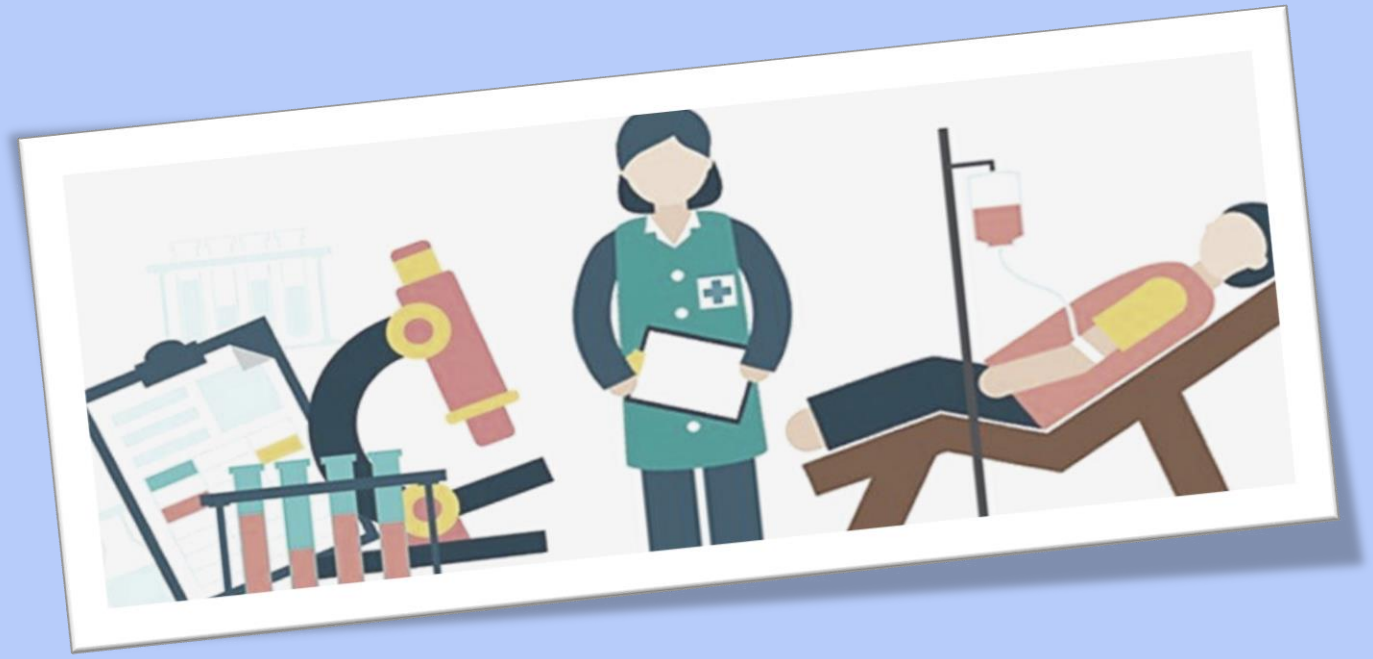

ENSAYOS CLÍNICOS DEL SERVICIO DE HEMATOONCOLOGÍA DEL HOSPITAL UNIVERSITARIO LA PAZ

Hospital Universitario La Paz
SaludMadrid
Hospital Carlos III
Hospital Cantoblanco

ÍNDICE

SPECIFIC SOLID TUMOURS:

Nervous System Tumours

Acronym	Clinical Trial Title	Phase	Type of Tumour	Patients Age	Promotor	EU CT Nº/code
DAY 101	LOGGIC/FIREFLY-2: A Phase 3, Randomized, International Multicenter Trial of DAY101 Monotherapy Versus Standard of Care Chemotherapy in Patients with Pediatric Low-Grade Glioma Harboring an Activating RAF Alteration Requiring First-Line Systemic Therapy	III	Glioma	less than 25 years	Day One Biopharmaceuticals, Inc	2022-001363-27
I3Y-MC-JPEH/Abemaciclib	A study to compare the efficacy and safety of abemaciclib plus temozolomide to temozolomide monotherapy in children and young adults with high-grade glioma following radiotherapy	II	Glioma	less than 21 years	Eli Lilly and Company	2022-502269-13-00
PNETS MB	Estudio prospectivo internacional de meduloblastoma (MB) en niños mayores de 3 a 5 años	NA	Meduloblastoma	3-5 years	University Medical Centre Hamburg-Eppendorf	2011-004868-30
SIOP EPENDIMOMA II	An international clinical program for the diagnosis and treatment of children, adolescents and young adults with ependymoma	NA	Ependymoma	less than 22 years	Centre Léon Bérard	2013-002766-39

Sarcomas

Acronym	Clinical Trial Title	Phase	Type of Tumour	Patients Age	Promotor	EU CT Nº/code
CABOSTAR	Effects of maintenance cabozantinib+BSC versus BSC in children and AYA with osteosarcoma.	**II**	Osteosarcoma	0-18 years	Ipsen Innovation	2023-506229-12-00
CAR4SARC	A Phase I Trial of Memory T Cells Expressing an NKG2D Chimeric Antigen Receptor in Children, Adolescents and Young Adults with Advanced Sarcoma	**I**	Sarcoma	≤ 40 years	Dr. ANTONIO PÉREZ-MARTÍNEZ	2019-004310-33
FAR-RMS	An overarching study for children and adults with Frontline and Relapsed RhabdoMyoSarcoma	**Ib**	RhabdoMyoSarcoma	>12 months and ≤25 years	University of Birmingham	2018-000515-24
INMUNOSARC 2	Phase I-II trial of sunitinib and/or nivolumab plus chemotherapy in advanced soft tissue and bone sarcomas	**I/II**	Sarcoma	12-80 years	Grupo Español de Investigación en Sarcomas (GEIS)	2016-004040-10
J1S-MC-JP04_ABEMACICLIB en Ewing	A Randomized, Open-Label, Phase 2 Study Evaluating Abemaciclib in Combination with Irinotecan and Temozolomide in Participants with Relapsed or Refractory Ewing's Sarcoma	**II**	Ewing's Sarcoma	1 to <40 years	Eli Lilly and Company	Document ID: VV-CLIN-074141

rEECCUR	International Randomised Controlled Trial of Chemotherapy for the Treatment of Recurrent and Primary Refractory Ewing Sarcoma	**II/III**	Ewing or Ewing-like sarcoma	≥2 years<30	Euro Erwing Consortium	2014-000259-99
SANKOMA	Ensayo Clínico Fase I/II, multicéntrico, abierto, de infusión de células NK activadas para el tratamiento de niños, adolescentes y adultos jóvenes con sarcomas	**I/II**	Sarcoma	0 y 40 años	ANTONIO PÉREZ-MARTÍNEZ	2016-003578-42
SYNERGIAS	Phase II multicohort trial of trabectedin and low-dose radiation therapy in advanced/metastatic sarcomas	**II**	Sarcoma	16-75 years	Grupo Español de Investigación en Sarcomas (GEIS)	2019-003103-36

GENERAL SOLID TUMOURS:

Acronym	Clinical Trial Title	Phase	Type of Tumour	Patients Age	Promotor	EU CT Nº/code
TAPISTRY	Tumor-agnostic precision immuno-oncology and somatic targeting rational for you (tapistry) phase ii platform trial	II	patients whose biomarker status is unknown and/or for patients with an ineligible local NGS test result	Patients aged □ 18 years: Eastern Cooperative Oncology Group (ECOG) Performance Status 0□2 Patients aged 16 to □ 18 years: Karnofsky score □ 50% Patients aged □ 16 years: Lansky score □ 50%	Roche	2020-001847-16
POPSTAR	Phase 1/2 Study of Cobolimab plus Dostarlimab in Pediatric and Young Adult Participants with Newly Diagnosed and Relapsed/Refractory Tumors	I/II	Solid Tumours	0≤21 años	GlaxoSmithKline Research	2024-511350-41-00

OTHER TYPES OF SOLID TUMOURS

Acronym	Clinical Trial Title	Phase	Type of Tumour	Patients Age	Promotor	EU CT Nº/code
PHITT	Paediatric Hepatic International Tumour Trial	**NA**	Hepatic tumour	Age ≤30 years.	University of Birmingham	2016-002828-85
HR-NEUROBLASTOMA	High-Risk Neuroblastoma Study 2 of SIOP-Europa-Neuroblastoma (SIOPEN)	**II**	Neuroblastoma	12-18 months old	Siopen R Net	2019-001068-31
MK-3475-667	Ensayo de fase II, abierto, multicéntrico y no controlado de MK-3475 (pembrolizumab) en niños y adultos jóvenes con linfoma de Hodgkin clásico recién diagnosticado y respuesta insuficiente (precoz lenta) a la quimioterapia de primera línea	**II**	Hodgkin lymphoma	≤3 - 25 years	Merck Sharp & Dohme LLC	2017-001123-53
UMBRELLA	UMBRELLA protocol	**NA**	Kidney cancer	All children, adolescents or young adults	International Society of Paediatric Oncology (SIOP) Renal Tumour Study Group (RTSG)	2016-004180-39

HAEMATOLOGICAL TUMOURS:

Acronym	Clinical Trial Title	Phase	Type of Tumour	Patients Age	Promotor	EU CT Nº/code
ALLTOGETHER	ALLTogether1 – A Treatment study protocol of the ALLTogether Consortium for children and young adults (0-45 years of age) with newly diagnosed acute lymphoblastic leukaemia (ALL)	III	Acute lymphoblastic leukaemia	0 - < 46 years	Karolinska University Hospital	2018-001795-38
AMBI2018	Childhood Ambiguous Leukemia Prospective Registry	NA	Acute leukemia of ambiguous lineage	before 18 years	Prospective I-BFM AMBI 2018 Registry	
ARI	Phase 2 study of the infusion of differentiated autologous T-cells from peripheral blood, expanded and transduced with a lentivirus to express a chimeric antigen receptor with anti-CD19 specificity (A3B1) conjugated with the co-stimulatory regions 4-1BB and CD3z (ARI-0001 cells) in children and adolescents aged 0-18 years with CD19+ acute lymphoblastic leukaemia resistant or refractory to treatment	II	Acute lymphoblastic leukaemia	0 to 18 years	Fundació Privada per a la Recerca i la Docència Sant Joan de Déu (FSJD)	2022-001101-52

B1931036_INOTUZUMAB *vs* R3	A prospective, randomized, open-label phase 2 study to evaluate the superiority of inotuzumab ozogamicin monotherapy versus allr3 for induction treatment of childhood high risk first relapse b-cell precursor acute lymphoblastic leukaemia	**II**	Acute lymphoblastic leukaemia	Between 1 and <18 years	Pfizer	2023-509810-13-00
CHIP-AML22	An open label complex clinical trial in newly diagnosed pediatric de novo AML patients	**II**	Acute myeloid leukemia	≥1 day and ≤ 18 years	NOPHO-DB-SHIP consortium	2023-504999-25-00
ESPhALL	International phase 3 trial in Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) testing imatinib in combination with two different cytotoxic chemotherapy backbones	**III**	Philadelphia chromosome-positive acute lymphoblastic leukemia	> 1 year and < 21 years	University of Milano-Bicocca	2017-000705-20
I-CML-Ped	International study of chronic myeloid leukemia (CML) treatment and outcomes in children and adolescents.	**NA**	Chronic leukemia myeloid	less than 18 years	Poitiers University Hospital	
INTERFANT 06	Guia de recomendaciones de la sehop para el tratamiento de la leucemia linfoblástica aguda o bifenotípica del lactante menor de 1 año	**NA**	Acute lymphoblastic leukaemia or biphenotypic	less than 1 year	Sociedad Española de Hematología y Oncología Pediátrica (SEHOP)	

IntReaLL-HR 2010	International Study for Treatment of High Risk Childhood Relapsed ALL 2010	**II**	HR relapsed ALL patients	less than 18 years	Charité - Universitätsmedizin Berlin	2012-000810-12
LBL 2018	International cooperative treatment protocol for children and adolescents with lymphoblastic lymphoma	**III**	Lymphoblastic lymphoma	less than 18 years	Universitätsklinikum Münster Albert-Schweitzer-Campus 1 48149 Münster	2017-001691-39
LCH	International collaborative treatment protocol for children and adolescents with langerhans cell histiocytosis	**III**	Langerhans cell histiocytosis	less than 18 years	St. Anna Kinderkrebsforschung (Children's Cancer Research Institute) Vienna, Austria	2011-001699-20
NOPHO	Research study for treatment of children and adolescents with acute myeloid leukaemia 0-18 years	**III**	Acute myeloid leukaemia	≤18 años	Västra Götaland Regionen Regionens Hus 462 80 Vänersborg Sweden	2012-002934-35
PROTEICO	Teicoplanin as Infection Prophylaxis in Pediatric Acute Myeloid Leukemia	**NA**	Acute Myeloid Leukemia	0-19 years	Princess Máxima Center for Pediatric Oncology, Heidelberglaan 25, 3584 CS Utrecht, the Netherlands	2020-000508-13
AC220-A-A202	A phase 1/2, multicenter, dose-escalating study to evaluate the safety, pharmacokinetics, pharmacodynamics, and efficacy of quizartinib administered in combination with re-induction chemotherapy, and as a single-	**I/II**	Acute Myeloid Leukemia	1 month-<18 years	DAIICHI SANKYO, INC.	EU CT NUMBER: 2023-510009-16-00

	agent continuation 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					
REALLCART	A Phase I Clinical Trial of CART cell therapy for refractory/ relapsed acute lymphoblastic leukemia with unmet needs in children, adolescents and young adults: feasibility and safety study (REALL_CART).	I	acute lymphoblastic leukemia	< 30 years	Fundación para la Investigación Biomédica del Hospital Universitario La Paz (FIBHULP)	2023-509723-41-01
RELATIVITY 069	Relatlimab + Nivolumab in Pediatric and Young Adult Lymphomas (RELATIVITY-069)	I/II	Classical Hodgkin Lymphoma and Non-Hodgkin Lymphoma	Part A only: 16 to 80 years. Part B, participant must be 0 to 30 years	Bristol-Myers Squibb Company	EU Trial Number: 2023-503715-14
SYRUS	A Phase 1/2 Study to Evaluate the Safety and Efficacy of AZD0486 in Adolescent and Adult Participants with Relapsed or Refractory B-Cell Acute Lymphoblastic Leukaemia	I/II	B-Cell Acute Lymphoblastic Leukaemia	Part A only: 16 to 80 years. If paediatric participant is ≥ 16 years, body weight should be ≥ 40 kg. Part B and Part C: 12 to 80 years. If participant is < 16 years, body weight should be ≥ 30 kg. If paediatric participant is ≥ 16	AstraZeneca AB	2023-505840-20-00

				years, body weight should be ≥ 40 kg.		

HAEMATOPOIETIC STEM CELL TRANSPLANT:

Acronym	Clinical Trial Title	Phase	Type of Tumour	Patients Age	Promotor	EU CT Nº/code
ALXN-TMA-314	Estudio para determinar si ravulizumab es eficaz, seguro y tolerable en adultos y adolescentes con microangiopatía trombótica (MAT) tras trasplante de células madre hematopoyéticas (TCMH).	III	microangiopatía trombótica (MAT) tras trasplante de células madre hematopoyéticas (TCMH)	From 28 days to 17 years	Alexion	2023-507850-33-00
BALDER	Trial of efficacy and safety of MC0518 versus best available therapy in patients with steroid-refractory acute graft-versus-host disease	II	Participant had a previous allogeneic HSCT as indicated for non-malignant (including inborn errors of metabolism, primary immunodeficiencies, haemoglobinopathies, and bone marrow failure syndromes) or haematological malignant disease or neuroblastoma.	≥ 28 days and < 18 years	Medac	2023-503952-28-00
PHINK	“Estudio fase I/II sobre infusión de células Natural Killer aloreactivas o estimuladas con IL-15 ex vivo	I/II	High Risk leukaemia	≤21 years	Fundación para la Investigación Biomédica del	2019-000911-10

	tras trasplante haploidéntico de progenitores hematopoyéticos en pacientes pediátricos con neoplasias hematológicas (PHINK)				Hospital Universitario La Paz (FIBHULP)	
PCYC	Phase 1/2 Dose Finding, Safety and Efficacy Study of Ibrutinib in Pediatric Subjects with Chronic Graft Versus Host Disease (cGVHD)	**I/II**	Chronic Graft Versus Host Disease	≥1 to <12 years	Pharmacyclics LLC	2017-004558-41
TAK-620-2004	Open-label, single-arm study to evaluate safety and tolerability, pharmacokinetics, and antiviral activity of maribavir for the treatment of pediatric and adolescent transplant recipients with CMV infection	**III**	Hematopoietic stem cell transplant (HSCT) or a solid organ transplant (SOT)	0-18 years	Takeda	2021-004279-15

OTHERS:

Acronym	Clinical Trial Title	Phase	Type of Tumour	Patients Age	Promotor	EU CT Nº/code
RELEASE	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	**I/II**	Pneumonia or lymphopenia related to COVID-19.	≤ 65 years	Fundación Para La Investigación Biomédica Del Hospital Universitario La Paz.	