

**Ensayos Clínicos Cabeza y Cuello abiertos a reclutamiento (Actualizado enero 2021)**  
**Fuente de información: Clinical trials.gov; EU Clinical Trials Register; REEC (AEMPS)**

| EudraCT Number                     | NCT     | CODIGO_ESTUDIO                  | TITULO_ESTUDIO  | FASE          | INDICACION  | ESTADO                      | MEDICACION   | CENTROS   | PROMOTOR   | ESPECIALIDAD                     |
|------------------------------------|---------|---------------------------------|---|---------------|---|-----------------------------|--|---|--|----------------------------------|
| <b>ENSAYOS PROMOVIDOS POR TTCC</b> |         |                                 |   |               |   |                             |  |   |  |                                  |
| 2019-002923-60                     | 4382109 | TTCC2019-01/CA209-7HE (NIVOTAX) | Phase II Multicenter Randomized Trial to Assess the Efficacy and Safety of First Line Pembrolizumab in Combination With Paclitaxel in Subjects With R/M HNSCC Unable for Cisplatin-based Chemotherapy (NIVOTAX).<br><b>1ª LINEA recurrent/metastatic</b>  | Phase II      | Patients unable for cisplatin-based chemotherapy  | RECLUTANDO                  | NIVOLUMAB  | ICD Hospitalet (BCN)<br>H.U.Clinic (BCN)<br>ICD_Badalona (BCN)<br>ICD_Girona (BCN)<br>H.Clinico (Madrid)<br>H.12 Octubre (Madrid)<br>H.U.La Fe (Valencia)<br>H.U.Miguel Serret<br>C.H. Navarra<br>H.C.I. Blesa (Zaragoza)<br>H.U.V. Rocio (Sevilla)<br>H.Regional (Málaga)<br>H.Clinico Valencia<br>H.U.V. Nieves (Granada)<br>H.U.V. Salud (Toledo)<br>C.H. Salamanca<br>C.O. Galicia(Coruña)<br>H.U. Donostia (S. Sebastian)<br>H.U.M. Valdehíta<br>H.U. Lucus Augusti(Lugo)<br>ICD Hospitalet (BCN)<br>H. del Mar (BCN)<br>ICD_Badalona (BCN)<br>ICD_Girona (BCN)<br>H.Clinico (Madrid)<br>H.12 Octubre (Madrid)<br>H.U.La Fe (Valencia)<br>H.U.M. Serrat(Zaragoza)<br>C.H. Navarra (Pamplona)<br>H.U.V. Valme (Sevilla)<br>H.R. Universitario (Málaga)<br>H.U. Lucus Augusti (Lugo)<br>H.U.V. Nieves (Granada)<br>H.U.V. Salud (Toledo)<br>C.H. Salamanca<br>C.O. Galicia(Coruña)<br>H.U. C. Marañón (Murcia) | TTCC   | Oncología_medica                 |
| N.A.                               | 467272  | TTCC-2019-02 (ERBITAX)          | Retrospective Study With Cetuximab Plus Paclitaxel as First Line for Recurrent and/or Metastatic SCCN (Squamous Cell Carcinoma of the Head and Neck): Real World Data.  | RETROSPECTIVE | The main objective will be to estimate the Progression-free survival (PFS) in patients treated with paclitaxel 80 mg/m2 as a starting dose, with weekly cetuximab that could have been switched to biweekly during the maintenance phase, as first line for recurrent and/or metastatic SCCN. | RECLUTANDO                  | Cetuximab<br>Paclitaxel  | ICD Hospitalet (BCN)<br>H. del Mar (BCN)<br>ICD_Badalona (BCN)<br>ICD_Girona (BCN)<br>H.Clinico (Madrid)<br>H.12 Octubre (Madrid)<br>H.U.La Fe (Valencia)<br>H.U.M. Serrat(Zaragoza)<br>C.H. Navarra (Pamplona)<br>H.U.V. Valme (Sevilla)<br>H.R. Universitario (Málaga)<br>H.U. Lucus Augusti (Lugo)<br>H.U.V. Nieves (Granada)<br>H.U.V. Salud (Toledo)<br>C.H. Salamanca<br>C.O. Galicia(Coruña)<br>H.U. C. Marañón (Murcia)   | TTCC   | Oncología_medica                 |
| <b>Otros PROMOTORES</b>            |         |                                 |   |               |   |                             |  |   |  |                                  |
| 2017-001139-38                     | 3765318 | MK3475-689                      | Estudio de fase III, aleatorizado y abierto para evaluar pembrolizumab como tratamiento neoadyuvante y en combinación con la asistencia habitual como tratamiento adyuvante en el carcinoma epidermoide de cabeza y cuello locorregionalmente avanzado (CECC LA), extríptable, en estado III-IVA.   | Phase II      | carcinoma epidermoide de cabeza y cuello locorregionalmente avanzado (CECC LA), extríptable, en estado III-IVA  | RECLUTANDO                  | Pembrolizumab<br>Cisplatin   | H.U. de Santiago<br>H.U.La Paz (Madrid)<br>H.U.V. Rocio (Sevilla)<br>ICD Hospitalet (BCN)<br>ICD_Badalona (BCN)<br>H.U. Vall d'Hebron (BCN)   | Merck Sharp & Dohme Corp.  | Oncología_medica<br>N=704        |
| 2019-003717-34                     | 4199104 | MK-7902-010                     | A Phase 3, Randomized, Placebo-controlled, Double-blind Clinical Study of Pembrolizumab (MK-3475) with or without Lenvatinib (E7080/MK-7902) to Evaluate the Safety and Efficacy of Pembrolizumab and Lenvatinib as 1L Intervention in a PD-1 Selected Population of Participants With Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma (R/M HNSCC) (LEAP-010).  | Phase II      | This is a study of pembrolizumab (MK-3475) with or without lenvatinib (E7080/MK-7902) as a first-line intervention in a PD-1 selected population with participants with recurrent or metastatic head and neck squamous cell carcinoma. ECDCG-1  | RECLUTANDO                  | Pembrolizumab<br>Lenvatinib  | ICD Hospitalet (BCN)<br>H.U. Vall d'Hebron (BCN)<br>H.12 Octubre (Madrid)<br>H.U.La Paz (Madrid)<br>H.U.L. Blesa (Zaragoza)<br>H.U. de Valme (Sevilla)  | Merck Sharp & Dohme Corp.  | Oncología_medica<br>N=500        |
| 2018-001437-40                     | 3719690 | KO-TIP-007                      | El estudio AIM-HN y SEQ-HN: Estudio pivotal no comparativo de 2 cohortes para evaluar la eficacia de tipifarnib en pacientes con carcinoma de células escamosas de cabeza y cuello (CCECC) con mutaciones de HRAS (AIM-HN) y el impacto de las mutaciones de HRAS en la respuesta a las terapias sistémicas de primera línea para el CCECC (SEQ-HN).  | Phase II      | Carcinoma de células escamosas de cabeza y cuello (CCECC) recurrente o metastásico con mutaciones en HRAS   | RECLUTANDO                  | Tipifarnib (oral)  | H. Vall d'Hebron (BCN)<br>H.U.Clinic (BCN)<br>H.U. Sant Pau (BCN)<br>ICD Hospitalet (BCN)<br>H. del Mar (BCN)<br>H. La Paz (Madrid)<br>H.12 Octubre (Madrid)<br>H.U. Sanchinarro (Madrid)<br>H.U.La Fe (Valencia)<br>H.U.M. Serrat (Zaragoza)<br>C.H. Navarra (Pamplona)<br>H.U. Santiago de Compostela<br>H.U.V. Rocio (Sevilla)<br>H.U.V. Victoria (Málaga)   | Kura Oncology, Inc   | Oncología_medica                 |
| 2019-003060-42                     | 4220866 | 1454-002                        | A Phase 3 Study in First-Line Metastatic or Unresectable, Recurrent Head and Neck Squamous Cell Carcinoma to Evaluate Intratumoral MK-1454 in Combination With Iv Pembrolizumab vs Iv Pembrolizumab Monotherapy   | Phase II      | The purpose of this study is to assess the efficacy and safety of intratumoral (IT) MK-1454 in PLUS pembrolizumab alone as a first line treatment of adults with metastatic or unresectable, recurrent head and neck squamous cell carcinoma (HNSCC).   | RECLUTANDO                  | MK-3475  | H.U. Vall d'Hebron (BCN)<br>H.Clinic (BCN)<br>H.U. Ramon y Cajal (Madrid)<br>H.U.V. Victoria (Málaga)   | Merck Sharp & Dohme Corp.  | Oncología_medica                 |
| 2019-002263-99                     | 4128426 | 209229                          | A Randomized, Double-blind, Adaptive, Phase II/III Study of GSK3359609 or Placebo in Combination With Pembrolizumab for First-Line Treatment of PD-L1 Positive Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma   | Phase II/III  | Study of GSK3359609 and Pembrolizumab in Programmed Death Receptor 3 ligand 1 Positive Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma (INDUCE-3)   | RECLUTANDO                  | GSK3359609 &<br>Pembrolizumab & Placebo  | H.U. Clinic (BCN)<br>H.U. Vall d'Hebron (BCN)<br>ICD Hospitalet (BCN)<br>H.U. Victoria (Málaga)<br>H.U. Ramon y Cajal (Madrid)<br>H.U.La Paz (Madrid)<br>H.U. Quiron (Madrid)<br>H.U.M. Serrat (Zaragoza)<br>H.U. Santiago de Compostela<br>H.Clinico Valencia<br>C.I.U. Victoria (Málaga)  | GlaxoSmithKline &<br>Merck Sharp & Dohme Corp.                                   | Oncología_medica                 |
| 2019-000569-19                     | 443811  | MK-7902-009                     | A Phase 2, Randomized, Open-label Three-arm Clinical Study to Evaluate the Safety and Efficacy of Lenvatinib (E7080/MK-7902) in Combination With Pembrolizumab Versus Physician's Choice Standard of Care Chemotherapy and Lenvatinib Monotherapy in Participants With Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma (R/M HNSCC) That Have Progressed After Platinum Therapy and Immunotherapy (PD-1/PD-L1 Inhibitors) (LEAP-009) 2ª línea añade Lenva & PD a inmunoterapia. | Phase II      | Recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC) which has progressed after treatment with both platinum therapy and most recently immunotherapy  | RECLUTANDO                  | Pembrolizumab<br>Lenvatinib  | ICD Hospitalet (BCN)<br>H.General Valencia<br>H.U. Vall d'Hebron (BCN)<br>H.U. Ramon y Cajal (Madrid)<br>H.U.V. Victoria (Málaga)   | Merck Sharp & Dohme Corp.  | Oncología_medica                 |
| 2018-002513-36                     | 3769506 | ASP-1929-301                    | A Phase 3, Randomized, Double-Arm, Open-Label, Controlled Trial of ASP-1929 Photodynamic Therapy Versus Physician's Choice Standard of Care for the Treatment of Locoregional, Recurrent Head and Neck Squamous Cell Carcinoma in Patients Who Have Failed or Progressed On or After at Least Two Lines of Therapy, of Which at Least One Line Must Be Systemic Therapy   | Phase II      | Locoregional, recurrent head and neck squamous cell carcinoma   | RECLUTANDO                  | ASP-1929<br>Photodynamic therapy   | H.U. Sanchinarro (Madrid)<br>H.U. Vall d'Hebron (BCN)   | Rakuten Aspyrian, Inc  | Oncología_medica                 |
| 2019-004770-26                     | 4590963 | D7310C00001                     | A Phase 3 Randomized, Double-blind, Multicenter, Global Study of Monalizumab or Placebo in Combination With Cetuximab in Patients With Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck Previously Treated With an Immune Checkpoint Inhibitor  | Phase II      | This is a randomized, double-blind, multicenter, global Phase 3 study to assess the efficacy and safety of monalizumab and cetuximab, compared to placebo and cetuximab, in patients with recurrent or metastatic head and neck cancer.   | Not yet recruiting (D9XKZ1) | Monalizumab<br>Cetuximab   | 6 Centros   | AstraZenca   | Oncología_medica                 |
| 2019-002745-38                     | 4539850 | GT1-419-202                     | An Open Label Multi-Center Study of the Effects of Supravital Disodium Mimetic GC4419 When Administered to Reduce the Incidence and Severity of Severe Oral Mucositis (SOM) Associated With Chemoradiotherapy for Locally Advanced, Non-Metastatic Head and Neck Cancer   | Phase II      | GT1-419-202 is a Phase 2 open-label study of the effects of GC4419 when administered IV in combination with IMRT/cisplatin to up to 70 subjects with head and neck cancer, who are at high risk for SOM.  | RECLUTANDO                  | GC4419   | C.H. Navarra<br>H.U. Vall d'Hebron (BCN)<br>H.U. Ramon y Cajal<br>H.12 Octubre (Madrid)<br>H.U. Cruces (Barakaldo)<br>H.U. Sanchinarro (Madrid)<br>C.I.U. Salamanca<br>H.U.V. Rocio (Sevilla)<br>H.U. Sanchinarro (Madrid)<br>ICD_Girona  | Galera Therapeutics, INC   | Oncología<br>Médica/Radioterapia |
| 2018-000789-13                     | 3669718 | ISA101B-HN-01-17                | Estudio de fase II, aleatorizado, con doble enmascaramiento y controlado con placebo de cetuximab en comparación con la combinación de cetuximab más (SA101B) en el tratamiento de sujetos con cáncer orofaríngeo (COF) Vp116 positivo resistente al platino  | Phase II      | Cáncer orofaríngeo (COF) Vp116-16 positivo resistente al platino  | RECLUTANDO                  | Human Papilloma Virus (HPV) type 16 E6/E7 synthetic long peptide (SLP) vaccine | ICD Hospitalet (BCN)<br>H.U.12 Octubre (Madrid)<br>H.C. San Carlos (Madrid)<br>H.U. Vall d'Hebron (BCN)<br>H.U. Clinic (BCN)<br>H.U. Vall d'Hebron (BCN)<br>H.U. Salamanca<br>H.U.V. Victoria (Málaga)<br>H.U.M. Valdehíta (Santander)  | ISA Therapeutics & V   | Oncología_medica                 |
| 2018-001095-38                     | 3799744 | ICO-VCN-HAN_2018                | A Phase 3 Study to Evaluate the Safety, Tolerability, and Efficacy of VCN-01 in Combination With Durvalumab (MEDI4736) in Subjects With Recurrent/ Metastatic Squamous Cell Carcinoma of the Head and Neck  | Phase I       | Metastasis & Recurrence   | RECLUTANDO                  | Genetic: VCN-01<br>Biological: Durvalumab                                      | ICD Hospitalet (BCN)<br>H.U. Vall d'Hebron (BCN)  | ICO Collaborator:<br>VCN Biosciences S.L.<br>BioClever 2005 S.L.<br>Astra Zeneca | Oncología_medica<br>N=20         |

| EudraCT Number  | NCT                     | CODIGO_ESTUDIO                 | TITULO_ESTUDIO  | FASE  | INDICACION  | ESTADO        | MEDICACION  | CENTROS   | PROMOTOR                               | ESPECIALIDAD                                     |
|---|-------------------------|--------------------------------|---|---|---|---------------|---|---|--|--|
| <a href="#">2019-003167-27</a>                                  | <a href="#">4196283</a> | M19-894                        | A Phase 1b, Multicenter, Open Label Study to Determine the Safety, Tolerability, Pharmacokinetics, and Preliminary Efficacy of ABBV 368 Plus Tisotumolod and Other Therapy Combinations in Subjects With Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma   | Phase I   | The main objective of this study is to assess safety, tolerability, and pharmacokinetics (PK) of ABBV 368 plus tisotumolod, ABBV 368 plus tisotumolod and nab-paclitaxel; and ABBV 368 plus tisotumolod, nab-paclitaxel, and ABBV 181 in participants with recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC).  | RECLUTANDO    | ABBV 368<br>Tisotumolod<br>Nab-paclitaxel<br>ABBV 181                       | H.Clinic (BCN)<br>ICD Hospital (BCN)<br>H.U.I2 Octubre (Madrid)<br>Start_Sanchinarro(Madrid)<br>H.U.V. Victoria (Málaga)<br>H.Clinico (Valencia)<br>H.U.Fuenteabrada (Madrid)                       | AbbVie / Idera<br>Pharmaceuticals, Inc | Oncologia_medica                                 |
| <a href="#">2018-003167-22</a>                                  | <a href="#">4156243</a> | M19-894                        | A Phase 1b, Multicenter, Open Label Study to Determine the Safety, Tolerability, Pharmacokinetics, and Preliminary Efficacy of ABBV 368 Plus Tisotumolod and Other Therapy Combinations in Subjects With Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma   | Phase I   | The main objective of this study is to assess safety, tolerability, and pharmacokinetics (PK) of ABBV 368 plus tisotumolod, ABBV 368 plus tisotumolod and nab-paclitaxel; and ABBV 368 plus tisotumolod, nab-paclitaxel, and ABBV 181 in participants with recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC).  | RECLUTANDO    | ABBV 368<br>Tisotumolod<br>Nab-paclitaxel<br>ABBV 181                       | H.U.Clinic ( BCN)<br>H.U.Fuenteabrada (Madrid)<br>H.U.I2 Octubre (Madrid)<br>Start_Sanchinarro (Madrid)<br>H.U.V. Victoria (Málaga)   | AbbVie                                 | Oncologia_medica                                 |
| <b>Tumores Sólidos con Cohorte de Cáncer de Cabeza y Cuello</b> |                         |                                |   |   |   |               |   |   |  |  |
| <a href="#">2018-001608-12</a>                                  | <a href="#">3649328</a> | IOV-COM-202                    | Estudio Fase II, multicéntrico de linfocitos de tumores autólogos (LN-144 o LN-145) en pacientes con SÓLID TUMORES.   | Phase II  | Tumores sólidos incluyendo melanoma metastásico avanzado (MM) o inresecable, carcinoma epidermoide de cabeza y cuello avanzado (CECC) y cáncer de pulmón no microcítico (CPNM) .<br>*LUNEA o SUCCESIVAS   | RECLUTANDO    | Prolekin<br>Pembrolizumab   | H.U.Vall d'Hebron (BCN)<br>ICD Duran i Reynals (BCN)<br>H.U.I2 Octubre (Madrid)<br>H.U.G. Marañón (Madrid)<br>F.J.Diaz (Madrid)<br>H.U.V. Málaga<br>H.U.Valdecilla (Santander)                      | Ionvance Biopharmaceutics, Inc         | Oncologia_medica                                 |
| <a href="#">2017-005076-26</a>                                  | <a href="#">3485209</a> | SGNTV-001                      | Open label phase 2 study of Tisotumab Vedotin for locally advanced or metastatic disease in SQUID TUMORS.   | Phase II  | 4_COHORTS: Colorectal , NSCLC, Exocirino pancreatic adenocarcinoma and SCCIN  | RECLUTANDO    | Tisotumab vedotin   | H.Vall d'Hebron (BCN)<br>H.U.Ramón y Cajal (Madrid)<br>H.U.Sanchinarro (Madrid)<br>H.QuironSalud (BCN)<br>ICD_Badajona (BCN)  | Seattle Genetics, Inc                  | Oncologia_medica                                 |
| <a href="#">2017-000241-49</a>                                  | <a href="#">3207867</a> | CNR178X2201                    | A Phase 2, Multi-center, Open Label Study of NRI178 in Combination With FOLFIRI in Patients With Selected Advanced Solid Tumors and Non-Hodgkin Lymphoma  | Phase II  | NSCLC, Non Small Cell Lung Cancer<br>RCC, Renal Cell Cancer<br>Pancreatic Cancer<br>Lutrothelial Cancer<br>Head and Neck Cancer<br>DLCL, Diffused Large B Cell Lymphoma<br>MS, Microsatellite Stable Colon Cancer<br>TNBC, Triple Negative Breast Cancer<br>Melanoma  | RECLUTANDO    | NRI178 & FOLFIRI  | H.U.Vall d'Hebron(BCN)  | Novartis Pharmaceuticals               | Oncologia_medica                                 |
| <a href="#">2015-003385-84</a>                                  | <a href="#">2568267</a> | GO40782 (RXDX-101-02)          | An Open Label, Multicenter, Global Phase 2 Basket Study of Entrectinib for the Treatment of Patients With Locally Advanced or Metastatic Solid Tumors That Harbor NTRK1/2/3, ROS1, or ALK Gene Rearrangements   | Phase II  | Breast Cancer, Cholangiocarcinoma<br>Colorectal Cancer, Head and Neck<br>Neuroblastoma, Large Cell,<br>Anaplastic Melanoma, Neuroendocrine,<br>Tumors Non-Small Cell Lung, Cancer Ovarian<br>Cancer Pancreatic, Cancer Ovarian<br>Thyroid, Cancer Primary Brain Tumors, Renal<br>Cell Carcinoma Sarcoma, Salivary Gland<br>Cancers Adult Solid Tumor  | RECLUTANDO    | ENTRECTINIB   | H.U.Vall d'Hebron (BCN)<br>H.U.I2 Octubre (Madrid)<br>H.U.Ramón y Cajal (Madrid)<br>START_Sanchinarro (Madrid)<br>H.U.Victoria (Málaga)<br>H.C.U. San Carlos (Madrid)<br>H.U.Virgen Rocío (Sevilla) | Hoffmann-La Roche / Ignyta, Inc        | Oncologia_medica                                 |
| <a href="#">2017-003182-94</a>                                  | <a href="#">3386721</a> | BP40234                        | An Open Label, Multicenter, Phase II Study to Evaluate the Therapeutic Activity of RO6874281, an Immunocytokine, Consisting of Interleukin-2 Variant (IL-2v) Targeting Fibroblast Activation Protein A (FAP), in Combination With Atezolizumab (anti-PD-L1), Administered Intravenously, in Participants With Advanced and/or Metastatic Solid Tumors   | Phase II  | Advanced/Metastatic Head and Neck,<br>Oesophageal and Cervical Cancers  | RECLUTANDO    | RO6874281<br>Atezolizumab Gemtuzumab<br>Vinorelbine                         | Clinica U Navarra<br>Hospital del Mar (BCN)<br>H.U.Vall d'Hebron (BCN)<br>START_F. Jimenez Diaz<br>START_Sanchinarro  | Hoffmann-La Roche                      | Oncologia_medica                                 |
| <a href="#">2018-001954-25</a>                                  | <a href="#">3625323</a> | TACTI-002/PO15<br>KEYNOTE-P978 | TACTI-002 (Two Active Immunotherapeutics): A multicenter, open label, Phase II study in patients with previously untreated unresectable or metastatic non-small cell lung cancer (NSCLC) or recurrent PD-L1 refractory NSCLC or with recurrent or metastatic squamous head and neck cancer (HNSCC) receiving the soluble LAG-3 fusion protein effigeneg alpha (IMP21) in combination with pembrolizumab (PD-1 antagonist) | Phase II  | Recurrent or metastatic squamous head and neck cancer (HNSCC)   | RECLUTANDO    | IMP21<br>Pembrolizumab  | H.Santa Creu i Sant Pau<br>ICD Badajona (BCN)<br>H.U.Vall d'Hebron(BCN)<br>F.J.Diaz (Madrid)  | IMMUTEP S.A.S                          | Oncologia_medica                                 |
| <a href="#">2015-003582-28</a>                                  | <a href="#">2576431</a> | LOXOTRX-15002<br>(NAVIGATE)    | A Phase 2 Basket Study of the Oral TRK Inhibitor Larotrectinib in Subjects With NTRK Fusion-positive Tumors   | Phase II  | The primary objective of this study is to investigate the efficacy of larotrectinib for the treatment of advanced solid tumors harboring a fusion of neurotrophic tyrosine receptor kinase (NTRK) of types 1-3 in children and adults.<br>*LUNEA<br>*HNSCC<br>Larotrectinib will be administered orally as capsule or liquid solution at a dose of 500 mg twice daily in continuing 28-day cycles.              | RECLUTANDO    | Larotrectinib (LOXO-101)  | H.U.Vall d'Hebron(BCN)<br>H.U.Sanchinarro(Madrid)<br>F.Jimenez Diaz (Madrid)<br>H.U.Valdecilla(Santander)<br>H.General de Valencia  | Boyer                                  | Oncologia_Medica<br>br-203<br>12 years and older |
| <a href="#">2015-004535-12</a>                                  | <a href="#">2389327</a> | KO-TIP-001                     | An Open Label Phase II Study of Tipifarnib in Advanced Non-Hemotological Malignancies With HRAS Mutations   | Phase II  | Squamous Cell Carcinoma Head and Neck<br>Cancer (HNSCC)RAS Mutant Tumor, Other<br>Squamous Cell Carcinoma (SCC) With HRAS<br>Mutant Tumor   | NO RECLUTANDO | Tipifarnib (oral)   | H.U.Vall d'Hebron (BCN)<br>START_Sanchinarro(Madrid)  | Kurita_Oncology, Inc                   | Oncologia_medica                                 |
| <a href="#">2018-003402-63</a>                                  | <a href="#">3317381</a> | GCT1046-01                     | First-in-human, Open-label, Dose-escalation Trial With Expansion Cohorts to Evaluate Safety of GEN1046 in Subjects With Malignant Solid Tumors  | PH1, first-in-human (FH) and an expansion part (phase 2a) | The trial is an open-label, multi-center safety trial of GEN1046. The trial consists of two parts, a dose escalation part (phase 1, first-in-human (FH) and an expansion part (phase 2a)). The expansion part of the trial will be initiated once the Recommended Phase 2 Dose (RP2D) has been determined.  | RECLUTANDO    | GEN1046   | Clinica U. de Navarra<br>H.U.Vall d'Hebron (BCN)<br>START_FJM(Madrid)<br>START_Sanchinarro, Madrid<br>H.Clinico de Valencia<br>H.U.I2 Octubre (Madrid)  | Genmab A/S                             | Oncologia_medica                                 |
| <a href="#">2019-003998-26</a>                                  | <a href="#">4426411</a> | GCT1044-01                     | First-in-human, Open-label, Dose-escalation Trial With Expansion Cohorts to Evaluate Safety of GEN1044 in Subjects With Malignant Solid Tumors  | First in human  | The trial is an open-label, multi-center safety trial of GEN1044. The trial consists of two parts: a dose escalation part (phase 1) and an expansion part (phase 2a). The expansion part of the trial will be initiated once the Recommended Phase 2 Dose (RP2D) has been determined from phase 1.  | RECLUTANDO    | Biological: GEN1044 (is an IgG1 bispecific antibody targeting CD3 and ST4). | H.Vall d'Hebron (BCN)<br>START_F. J.Diaz (Madrid)   | Genmab/AbbVie                          | Oncologia_medica                                 |
| <a href="#">2016-002219-16</a>                                  | <a href="#">2388260</a> | M15-862                        | A Multicenter, Phase 1, Open-label, Dose Escalation Study of ABBV 927 and ABBV 181, an Immunotherapy, in Subjects With Advanced Solid Tumor   | Phase I   | Advanced, solid tumors, squamous cell cancer of the head and neck, pancreatic cancer, non-small cell lung cancer, melanoma  | RECLUTANDO    | ABBV 927 & ABBV 181   | START_Sanchinarro, Madrid<br>H.U.P. de Hierro (Madrid)<br>H.U.I2 FE (Valencia)<br>START_F. J.Diaz (Madrid)  | AbbVie                                 | Oncologia_medica                                 |
| <a href="#">2019-000446-36</a>                                  | <a href="#">3894618</a> | SL01-DE-101                    | Phase 1 Dose Escalation and Dose Expansion Study of an Agonist Redirected Checkpoint Fusion Protein, SL-279252 (PD-1-Fc-OS406), in Subjects With Advanced Solid Tumors or Lymphomas   | Phase I   | Squamous Cell Carcinoma of the Head and Neck, Melanoma, Small Cell Lung Cancer, Laryngeal Carcinoma, Gastric Adenocarcinoma, Gastroesophageal Junction Adenocarcinoma, Squamous Cell Carcinoma of the Anus, Squamous Cell Carcinoma of the Cervix, Squamous Cell Carcinoma of the Stomach, Cell Carcinoma, Multiple Myeloma, Diffuse Large B Cell Lymphoma, Mismatch Repair Deficient or MSI High Solid Tumors. | RECLUTANDO    | SL-279252   | H.U.Vall d'Hebron (Barcelona)   | Shattuck Labs, Inc.                    | Oncologia_medica                                 |
| UK  | <a href="#">1351103</a> | CLG694942101                   | A Phase I, Open-label, Dose Escalation Study of Oral LGK974 in Patients With Malignancies Dependent on Wnt Ligands  | Phase I   | This primary purpose of this study is to find the recommended dose of LGK974 as a single agent and in combination with FOLFIRI that can be safely given to adult patients with selected solid malignancies for whom no effective standard treatment is available.   | RECLUTANDO    | Drug: LGK974<br>Biological: PR001   | 2 Sites Barcelona<br>2 Sites Madrid   | Novartis Pharmaceuticals               | Oncologia_medica                                 |
| <a href="#">2018-004314-16</a>                                  | <a href="#">4314113</a> | SC103                          | A Multicenter Open-label Phase 1/2b Study to Evaluate the Safety and Preliminary Efficacy of SO-C101 as Monotherapy and in Combination With Pembrolizumab in Patients With Selected Advanced/Metastatic Solid Tumors  | Phase I   | HNSCC & Thyroid. A multicenter open-label phase 1/2b study to evaluate the safety and preliminary efficacy of SO-C101 as monotherapy and in combination with pembrolizumab in patients with selected advanced/metastatic solid tumors   | RECLUTANDO    | SO-C101<br>Pembrolizumab  | H.U.Vall d'Hebron(BCN)  | SOTIO                                  | Oncologia_medica                                 |
| <a href="#">2016-003429-41</a>                                  | <a href="#">3291002</a> | CV-8102-008                    | Phase I Study of Intratumoral CV8102 in Patients With Advanced Melanoma, Squamous Cell Carcinoma of the Skin, Squamous Cell Carcinoma of the Head and Neck, or Adenoid Cystic Carcinoma   | Phase I   | This study evaluates intratumoral administration of CV8102 in patients with advanced melanoma, squamous cell carcinoma of the skin, squamous cell carcinoma of the head and neck, or adenoid cystic carcinoma.  | RECLUTANDO    | Biological: CV8102<br>Biological: CV8102 + anti-PD-1 therapy                | H.U.Vall d'Hebron (BCN)<br>H.U.Victoria (Málaga)  | CureVac AG / Syneco Health             | Oncologia_medica                                 |

| EudraCT Number                 | NCT                     | CODIGO_ESTUDIO  | TITULO_ESTUDIO   | FASE        | INDICACION   | ESTADO                        | MEDICACION                                    | CENTROS  | PROMOTOR   | ESPECIALIDAD           |
|--------------------------------|-------------------------|-----------------|--|-------------|--|-------------------------------|---|--|--|------------------------|
| <a href="#">2019-004748-31</a> | <a href="#">4354107</a> | SGMTGT-001      | A Phase I Study of SEA-TGT (SGN-TGT) in Subjects With Advanced Malignancies  | Phase I     | Part C will study how well SEA-TGT with pembrolizumab works to treat solid tumors. Pembrolizumab is a drug that can be used to treat these types of cancer.  | RECLUTANDO                    | SEA-TGT<br>Pembrolizumab                      | H.Vall d'Hebron (BCN)  | Seagen Inc.                                      | Oncologia_medica       |
| <a href="#">2017-001473-23</a> | <a href="#">3289962</a> | GO39733         | A phase Ia/Ib, open-label, dose escalation study of the safety and PKs of ROT198457 as a single agent and in combination with Atezolizumab in patients with locally advanced or metastatic Tumors.   | Phase Ia/Ib | 8_COHORTS: Melanoma, Bladder Ca, NSCLC, Colorectal, Triple Negative Breast Ca, Renal Ca, H&N Cancer, other Solid Cancers.  | RECLUTANDO                    | Atezolizumab<br>ROT198457                     | H.U.Vall d' Hebron (BCN)<br>C.IJ.Navarra(Pamplona)   | Genentech,INC                                    | Oncologia_medica       |
| <a href="#">2017-001553-14</a> | <a href="#">3150810</a> | BGB-290-103     | A Phase 1b Study to Assess the Safety, Tolerability and Clinical Activity of BGB-290 in Combination With Temozolomide (TMZ) in Subjects With Locally Advanced or Metastatic Solid Tumors   | Phase Ib    | The primary objective of this study is to determine the safety and tolerability of pamparib, the maximum tolerated dose (MTD) or maximum administered dose (MAD) for pamparib combined with TMZ, to select the recommended Phase 2 dose (RP2D) and schedule of pamparib in combination with TMZ, and to determine the antitumor activity of pamparib in combination with TMZ.    | RECLUTANDO                    | Pamparib<br>Temozolomide                      | H.Vall d'Hebron (BCN)<br>ICD-Hospital (BCN)<br>Start, F.J. Diaz (Madrid)<br>Start_Sanchinarro (Madrid)<br>H.Clinico (Valencia)   | BeGene   | Oncologia_medica       |
| <a href="#">2018-001456-34</a> | <a href="#">3543813</a> | CTMX-M-2029-001 | A Phase 1-2, First-in-Human Study of CX-2029 in Adults With Metastatic or Locally Advanced Unresectable Solid Tumors or Diffuse Large B-cell Lymphomas (PROCLAIM-CX-2029)  | Phase I/II  | The purpose of this first-in-human study of CX-2029 is to characterize the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD) and antitumor activity of CX-2029 in adult subjects with metastatic or locally advanced unresectable solid tumors or diffuse large B-cell lymphoma (DLBCL). PROCLAIM-PRObody Clinical Assessment in Man CX-2029 clinical trial 001 | RECLUTANDO                    | CX-2029                                       | H.Clinic(BCN)<br>H.U.La Paz (Madrid)<br>Start_Sanchinarro (Madrid)   | CytomX Therapeutics                              | Oncologia_medica       |
| <a href="#">2018-004771-12</a> | <a href="#">6009523</a> | CTN015581201    | A Phase Ib, Open-label, Multi-center Study to Characterize the Safety, Tolerability, and Preliminary Efficacy of TNO155 in Combination With Spartinolizumab or Ribociclib in Selected Malignancies   | Phase Ib    | This study is a Phase Ib, multi-center, open-label study of TNO155 in combination with spartinolizumab or ribociclib with a dose escalation part followed by a dose expansion part in adult subjects with advanced solid tumors.   | RECLUTANDO                    | TNO155<br>Spartinolizumab<br>Ribociclib       | H.Vall d'Hebron (BCN)  | Novartis Pharmaceuticals                         | Oncologia_medica       |
| <a href="#">2016-001860-12</a> | <a href="#">2900651</a> | CMAX683X101     | A phase VII, multicenter, open-label study of MAX683 in adult patients with advanced malignancies  | Phase VII   | H&N cancer subjects who have radiographically progressed during or following prior platinum-containing chemotherapy. Prior treatment with ICs (anti-PDL or anti-IPD-L1) is allowed if given in combination with chemotherapy.  | RECLUTANDO                    | MAX683  | H.U.12 Octubre (Madrid)  | Novartis Pharmaceuticals                         | Oncologia_medica       |
| <a href="#">2019-000474-45</a> | <a href="#">3893955</a> | M19-087         | A Phase 1, Multicenter, Open-Label Study to Determine the Safety, Tolerability, Pharmacokinetics, and Preliminary Efficacy of ABBV-927 and ABBV-368 With and Without ABBV-181 in Subjects With Locally Advanced or Metastatic Solid Tumors             | Phase I     | Advanced Solid, Tumors Triple-Negative Breast Cancer (TNBC) Non-small cell lung cancer (NSCLC), Head and Neck Squamous Cell Carcinomas (HNSCC), Metastatic Solid Tumors  | Not yet recruiting (01/14/20) | ABBV-927<br>ABBV-368<br>ABBV-181<br>Docetaxel | H.Vall d'Hebron (BCN)<br>ICD-Hospital (BCN)<br>Start, F.J. Diaz (Madrid)<br>START_Sanchinarro (Madrid)   | AbbVie   | Oncologia_medica       |
| <a href="#">2020-000075-20</a> | <a href="#">4465447</a> | REG569-ONC-1933 | A Phase I Study of REGN569, an Anti-GTR mAb, With Cemiplimab in Patients With Advanced Solid Tumors  | Phase I     | For dose escalation cohorts, the primary objective is to evaluate the safety and tolerability of REGN569 as monotherapy lead-in and in combination with cemiplimab   | Not yet recruiting (20/01/21) | REGN569<br>Cemiplimab                         | 4Centros Madrid<br>2Centros Barcelona  | Regeneron Pharmaceuticals                        | Oncologia_medica       |
| <a href="#">UK</a>             | <a href="#">4504669</a> | D995C00001      | A Phase I First-in-Human Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics and Efficacy of AZD8701 Administered Intravenously as Monotherapy and in Combination With Durvalumab (MEDI4736) in Participants With Advanced Solid Tumours. | Phase I     | The purpose of this study is to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, Immunogenicity and Antitumor Activity of AZD8701 Alone and in Combination with Durvalumab (MEDI4736) in Adult Subjects with Select Advanced Solid Tumors  | Not yet recruiting (20/01/21) | AZD8701                                       | 1 Site Barcelona<br>1 Site Pamplona  | AstraZeneca                                      | Oncologia_medica       |
| <a href="#">2019-003474-35</a> | <a href="#">3138889</a> | 16-214-05       | A Phase I/2, Open-Label, Multicenter Study to Investigate the Safety and Preliminary Efficacy of NKTR-214 in Combination With Pembrolizumab in Patients With Locally Advanced or Metastatic Solid Tumors   | Phase I/II  | This study is to assess the safety and tolerability, and to assess the preliminary clinical benefit of NKTR-214 when combined with pembrolizumab (KEYTRUDA®).  | Not yet recruiting (20/01/21) | NKTR-214<br>Pembrolizumab                     | 7 Sites  | Nektar Therapeutics                              | Oncologia_medica       |
| <a href="#">2018-001146-34</a> | <a href="#">3203022</a> | 8374-CL-0101    | A Phase 1b Study of ASP8374, an Immune Checkpoint Inhibitor, as a Single Agent and in Combination With Pembrolizumab in Subjects With Advanced Solid Tumors  | Phase I     | Advanced and serious forms of cancer such as head and neck cancers, non-small cell lung cancer, prostate cancer, ovarian cancer, colorectal cancer and gastric cancer  | NO RECLUTANDO                 | ASP8374<br>Pembrolizumab                      | H.U.Clinic(BCN)<br>H.U.Vall d' Hebron (BCN)<br>ICD_Hospital (BCN)<br>Start_Sanchinarro(Madrid)<br>Start, F.J. Diaz (Madrid)<br>H del Mar(BCN)<br>H.U.V. Victoria(Málaga)<br>H.U.U. Victoria(Sevilla)<br>H.U.G. Marañon(Madrid) | Astellas Pharma Global Development INC Astellas. | Oncologia_medica       |
| <a href="#">2016-002799-20</a> | <a href="#">3260023</a> | TG4001.12       | A phase Ib/II trial evaluating the combination of TG4001 and avelumab in patients with HPV-16 positive recurrent or metastatic malignancies and expansion cohort to oropharyngeal squamous cell carcinoma of the head and neck (SCCHN)                 | Phase Ib/II | HPV-16 positive recurrent or metastatic malignancies including oropharyngeal squamous cell carcinoma of head and neck, cervical cancer, vulvar cancer, vaginal cancer, penile cancer, anal cancer  | NO RECLUTANDO                 | TG4001<br>Avelumab                            | H.U.12 Octubre (Madrid)<br>H.U.Clinico (Madrid)<br>ICD_Batolona (BCN)<br>H.U.U. Victoria (Málaga)<br>H.U.U. Alicer (Granada)<br>H.U.General d'Valencia   | TRANSEGENE                                       | Oncologia_medica       |
| <a href="#">UK</a>             | <a href="#">4361179</a> | 2019-003825-56  | An Exploratory Prospective, Open-label, Unicentric Study With Cross-over Design: Comparing LymphoScan™ vs. Albumin Nanocolloid for Image-Guided Sentinel Lymph Node Mapping in Head and Neck, Melanoma and Breast Cancer. (SENTINELSEES)               | Phase IV    | Comparison of the concordance of albumin nanocolloid and LymphoScan™ in the detection of lymph nodes of primary and secondary stage drainage by performing two lymphogrammagrams   | Not yet recruiting (01/14/20) | LymphoScan<br>Nanocolloid                     | H.U.Clinic (BCN)   | Fundacion Clinic per la Recerca Biomedica        | Oncologia_medica       |
| <a href="#">UK</a>             | <a href="#">4145180</a> | 0045-N-16       | Effectiveness of a Physical Recovery Program for Head and Neck Cancer Patients (3C-CLIDATE)  | Prospectivo | This project intends to carry out an experimental randomized controlled study with 84 patients treated of head and neck cancer who will be assigned randomly to the study groups: a) manual therapy program or, b) control group. The assessment refers to a baseline form (at the beginning of the study), at 6 weeks and at 6 months of patient follow-up.                     | RECLUTANDO                    | Manual therapy                                | Universidad de Granada   | Universidad de Granada                           | Oncologia              |
| <a href="#">UK</a>             | <a href="#">4110977</a> | RAREST-02       | Radiotherapy Related Skin Toxicity: A Reminder App to Reduce Radiation Dermatitis Rates in Patients With Head and Neck Cancer  | UK          | The goal of this trial is to investigate whether the addition of a reminder app to standard care leads to a reduction of dermatitis and oral mucositis during radiochemotherapy for locally advanced squamous cell carcinoma of the head and neck (SCCHN).   | RECLUTANDO                    | Mobile application (reminder app)             | H.U.de Cruces (Bilbao)<br>H.U.U. de Fej (Valencia)   | University Hospital Schleswig-Holstein           | Oncologia_radioterapia |
| <a href="#">2018-003352-20</a> | <a href="#">3768063</a> | BO40729         | An Open Label, Multicenter Extension Study in Patients Previously Enrolled in a Gemtuzumab and F. Hoffmann-La Roche Ltd Sponsored Atezolizumab Study (IMBrella B)  | Phase IV    | Squamous cell carcinoma of head and neck, Solid Tumors, NSCLC, Urothelial carcinoma, Renal cell carcinoma  | RECLUTANDO                    | Atezolizumab                                  | C.IJ.Navarra<br>H.U.Sanchinarro (Madrid)<br>H.Sabadell (BCN)   | Hoffmann-La Roche                                | Oncologia_medica       |