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3.4.11 Translational Hepatology



Publications: 12 | Q1: 9

COMPOSITION

Francisco Javier García-Samaniego Rey.
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- **Marina Camblor Murube.** *Investigadora Predoctoral. Universidad Autónoma de Madrid*
- **Antonio Madejón Seiz.** *Investigador Postdoctoral. CIBERehd*
- **Antonio Olveira Martín.** *Facultativo Especialista de Área en Hepatología. Hospital Universitario La Paz*
- **Miriam Romero Portales.** *Facultativo Especialista de Área en Gastroenterología. Hospital Universitario La Paz*

STRATEGIC OBJETIVES

- The laboratory and the Hepatology Department of the hospital actively participate in the national optimization of viral hepatitis micro-elimination processes. This involves implementing rapid screening pathways and systems, quickly referring infected patients to the hospital, and integrating them into the corresponding care cascade. This objective requires inter-hospital collaboration, as well as, especially importantly, collaboration with Primary Care Centers and Drug Addiction Treatment Centers. While the goal is to implement this strategy for all liver virus infections, the model is specifically designed for the HCV micro-elimination system. The Alliance for the Elimination of Viral Infections, led by the group's Principal Investigator, Dr. García-Samaniego, actively participates in this initiative.
- Implementation of sequence analysis systems using NGS techniques for the study of viral evolution.
- Development of collaborations with basic research teams specializing in the study of epigenetic modifications at the histone level, and the composition of the intestinal microbiome.

RESEARCH LINES

- The main focus of the group's work is on the study of hepatitis virus infections [hepatitis B (HBV), C (HCV), delta (HDV) and E (HEV)] and related chronic liver disease, addressing both clinical and basic aspects:

  1. Analysis of the role of epigenetic modifications induced by hepatitis virus infection in the evolution of liver disease and the development of liver cancer, before and after antiviral treatment. Project under development in collaboration with the Department of Biochemistry of the Faculty of Medicine of the Autonomous University of Madrid (UAM) and the Virology Laboratory of the Severo Ochoa Molecular Biology Center.

  2. Design of predictive algorithms for the development of hepatocellular carcinoma in patients with chronic hepatitis C, treated and cured.

  3. Study of the epidemiological situation and optimization of the care cascade for patients with hepatitis delta virus (HDV) infection. Project in collaboration with the Hospital Clínic of Barcelona and the Hospital Infanta Leonor of Madrid, and funded by the HDV DESCRIBE program sponsored by Gilead Sciences.

  4. Study of the variability of the VHD genome in the Spanish population. Impact of variability on newly designed therapies.

  5. Development of HCV micro-elimination strategies through the optimization and implementation of HCV detection and quantification systems at diagnostic points.

  6. Study of the influence of pre-existing liver disease on the evolution of COVID-19.

IdiPAZ Instituto de Investigación Hospital Universitario La Paz

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RESEARCH ACTIVITY

Publications

- **Alonso-Castellano P, Mariño Z, Tugores A, Olveira A, Ampuero J, Berenguer M, Fernández-Ramos JR, Moreno-Planas JM, Lázaro-Ríos M, Masnou H, González-Diéguez ML, Pinazo-Bandera JM, Molina-Pérez E, Hernández-Guerra M, Romero-Gutiérrez M, Fernández-Álvarez P, Muñoz C, Lorente S, Cachero A, Delgado-Blanco M, Vargas V, Gómez-Camarero J, Cuenca F, Ibáñez-Samaniego L, Fernández-Bermejo M, Álvarez-Suárez B, Iruzubieta P, Arencibia-Almeida A, García-Villarreal L.** Genetic map of Wilson disease in Spain-A great tool to improve diagnosis and screening. Rev Esp Enferm Dig. 2025; 117(5): 249-55. Article. IF: 4.8; Q1
- **Alonso-Castellano P, Tugores A, Mariño Z, Olveira A, Berenguer M, Huarte MP, Fernández-Ramos JR, Lázaro-Ríos M, González-Diéguez ML, Moreno-Planas JM, Hernández-Guerra M, Fernández-Álvarez P, Delgado-Blanco M, Pinazo-Bandera JM, Romero M, Ampuero J, Masnou-Ridaura H, Cachero A, Vargas V, Gómez-Camarero J, Morillas-Ariño MJ, Molina-Pérez E, Miralpeix A, García-Villarreal L.** Low penetrance of frequent ATP7B mutations explains the low prevalence of Wilson disease. Lessons from real-life registries. Digest Liver Dis. 2025; 57(2): 443-9. Article. IF: 4.9; Q1
- **Berenguer M, García-Villarreal L, Olveira A, Pérez EM, Planas JMM, Romero-Gutiérrez M, Bandera JMP, Ridaura HM, Iruzubieta P, Diéguez MLG, Ampuero J, Ramos JRF, Muñoz C, Almeida AA, Lorente S, Blanco MD, Santamaría DB, Delgado MP, Cachero A, Guerra MH, Camarero JG, Rojas SG, Ríos ML, Soria IC, Carrión G, Bono A, Miralpeix A, Castellano PA, Mariño Z.** Predictive value of liver enzymes in long-term prognosis of hepatic Wilson disease: results from the Wilson AEEH registry. Orphanet J Rare Dis. 2025; 20(1): 288. Article. IF: 3.6; Q2
- **Chafino S, Tarancón-Díez L, Hurtado-Gallego J, Flores-Piñas M, Alcolea S, Olveira A, Navarro ML, Fernández-Arroyo S, Viladés C, Montes ML, Vidal F, Peraire J, Rull A, Sainz T.** Metabolomics for searching non-invasive biomarkers of metabolic dysfunction-associated steatotic liver disease in youth with vertical HIV. Commun Med (Lond). 2025; 5(1): 433. Article. IF: 7.4; Q1
- **Cuadros M, Abadía M, Castillo P, Martín-Arranz MD, Gonzalo N, Romero M, García-Sánchez A, García-Samaniego J, Olveira A, Ruiz-Cantador J, González-Fernández O, Ponz I, Merás P, Merino C, Rodríguez-Chaverri A, Balbacid E, Froilán C.** Role of transient elastography in the diagnosis and prognosis of Fontan-associated liver disease. World J Gastroentero. 2025; 31(11): 103178. Article. IF: 7.7; Q1
- **Hiebert-Suwondo L, Manning J, Tohme RA, Buti M, Kondili LA, Spearman CW, Hajarizadeh B, Turnier V, Lazarus J, Grebely J, Dore GJ, Waked I, Ward JW, (García-Samaniego J).** A 2024 global report on national policies, programmes, and progress towards hepatitis C elimination: findings from 33 hepatitis elimination profiles. Lancet Gastroenterol Hepatol. 2025; 10(7): 685-700. Article. IF: 39.1; D1
- **Hiebert-Suwondo L, Manning J, Tohme RA, Buti M, Kondili LA, Spearman CW, Prabdial-Sing N, Turnier V, Lazarus J, Waked I, Ward JW, (García-Samaniego J).** A 2024 global report on national policy, programmes, and progress towards hepatitis B elimination: findings from 33 hepatitis elimination profiles. Lancet Gastroenterol Hepatol. 2025; 10(7): 671-84. Article. IF: 39.1; D1
- **Laue T, Ballester MP, Meoli L, Grabitz C, Uson E, D'Antiga L, McLin V, Pujadas M, Carvalho-Gomes A, Sahuco I, Bono A, D'Amico F, Viganò R, Diago E, Lanseros BT, Inglese E, Vazquez DM, Broekhoven A, Kikkert M, Morales SPT, Myeni SK, Riveiro-Barciela M, Palom A, Zeni N, Brocca A, Cussigh A, Cmet S, Escudero-García MD, Stocco M, Natola LA, Ieluzzi D, Paon V, Sangiovanni A, Farina E, Dibenedetto C, Sánchez-Torrijos Y, Lucena-Varela A, Román E, Sánchez E, Sánchez-Aldehuelo R, López-Cardona J, Jeyanesan D, Morocho AE, Canas-Pérez I, Eastgate C, Di Cola S, Lapenna L, Zaccherini G, Bongiovanni D, Riva A, Sharma R, Tsou HLP, Harris N, Zanaga P, Sayaf K, Hossain S, Crespo J, Robles-Diaz M, Madejón A, Degroote H, Korenjak M, Verhelst X, García-Samaniego J, Andrade RJ, Iruzubieta P, Wright G, Caraceni P, Merli M, Patel VC, Gander A, Albillos A, Soriano G, Donato MF, Sacerdoti D, Toniutto P, Buti M, Duvoux C, Grossi PA, Berg T, Polak WG, Puoti M, Bosch-Comas A, Belli LS, Burra P, Russo FP, Coenraad M, Calleja JL, Perricone G, Chokshi S, Berenguer M, Clària J, Moreau R, Fernández J, Arroyo V, Angeli P, Sánchez-Garrido C, Ampuero J, Piano S, Nicastro E, Rock N, Shawcross D, Edwards L, Mutschler F, Melk A, Mehta G, Baumann U, Jalan R.** Pediatric liver and kidney transplant recipients demonstrate greater serological response to SARS-CoV-2 Vaccination Than Adults. Transplant Direct. 2025; 11(5): e1787. Article. IF: 2.2; Q2
- **Pocurull A, Broquetas T, Hoyas E, Rodríguez M, Miquel M, Rodriguez M, Roig CA, Herms Q, Rodríguez-Tajes S, García-Samaniego J, Suárez E, Buti M, Forns X, Carrión JA, Lens S.** Determinants of HBsAg loss after nucleos(t)ide discontinuation in a prospective cohort of HBeAg-negative caucasian patients. Liver Int. 2025; 45(11): e70371. Article. IF: 6.2; Q1
- **Razavi HA, Waked I, Qureshi H, Kondili LA, Duberg AS, Aleman S, Tanaka J, Lazarus JV, Low-Beer D, Abbas Z, Abou Rached A, Aghemo A, Aho I, Akarca US, Al-Busafi SA, Al-Hamoudi WK, Al-Naamani K, Alaama AS, Aldar MM, Alghamdi M, Gonzalez MA, Alserehi H, Anand AC, Asselah T, Assiri AM, Athanasakis K, Atugonza R, Ben-Ari Z, Berg T, Brandao-Mello CE, Brown ASM, Brown KA, Brown RS , Bruggmann P, Brunetto MR, Buti M, Cheinquer H, Christensen PB, Chulanov V, Garza LEC, Coffin CS, Coppola N, Craxi A, Crespo J, Cui FQ, Dalgard O, De La Torre A, De Ledinghen V, Dieterich D, Drazilova S, Dufour JF, El-Kassas M, Elbadri M, Esmat G, Mur RE, Eurich B, Faini D, Ferreira PRA, Flisiak R, Frankova S, Gaeta GB, Gamkrelidze I, Gane EJ, Garcia V, García-Samaniego J, Gemilyan M, Gottfredsson M, Gschwantler M, Gurski APM, Hajarizadeh B, Hamid SS, Hatzakis A, Hercun J, Hockicková I, Huang JF, Hunyady B, Hutchinson SJ, Ishikawa N, Izumi K, Izzi A, Janicko M, Jarcuska P, Jeruma A, Johannessen A, Kaliaskarova KS, Kao JH, Kielland KB, Kodjoh N, Kottilil S, Kristian P, Kwo PY, Lagging M, Lam H, Lázaro P, Lee MH, Lens S, Liakina V, Lim YS, Makara M, Manns M, Manzengo CM, Memon S, Mendes-Correa MC, Messina V, Midgard H, Murphy N, Musabaev E, Naveira MCM, Nde H, Negro F, Nim N, Ocama P, Olafsson S, Omuemu CE, Pamplona J, Pan CQ, Papatheodoridis GV, Pimenov N, Poustchi H, Quaranta MG, Ramji A, Rautiainen H, Razavi-Shearer DM, Razavi-Shearer K, Ridruejo E, Ríos-Hincapié CY, Sadirova S, Sanai FM, Sarrazin C, Sarybayeva G, Schréter I, Seguin-Devaux C, Sereno LS, Shiha G, Smith J, Soliman R, Sonderup MW, Spearman CW, Stauber RE, Stedman CAM, Sypsa V, Tacke F, Terrault NA, Tolmane I, Van Welzen B, Voeller AS, Waheed Y, Wallace C, Whittaker RN, Wong VWS, Ydreborg M, Yesmembetov K, Yu ML, Zeuzem S, Zuckerman E.** Number of people treated for hepatitis C virus infection in 2014-2023 and applicable lessons for new HBV and HDV therapies. J Hepatol. 2025; 83(2): 329-47. Article. IF: 40.1; D1

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- **Rodríguez-Tajes S, Palom A, Giráldez-Gallego A, Moreno A, Urquijo JJ, Rodríguez M, Alvarez-Argueelles M, Diago M, García-Eliz M, Fuentes J, Martinez-Sapina AM, Castillo P, Casado M, Pérez-Campos E, Muñoz R, Hernández-Conde M, Morillas RM, Granados R, Miquel M, Morillas MJ, Garcia-Retortillo M, Carrión JA, Moreno JM, Montón C, González-Santiago JM, Lorente S, Cabezas J, Mateos B, Vázquez-Rodríguez S, Díaz-Fontenla F, Pinazo JM, Delgado M, Pérez-Palacios D, Horta D, Fernández-Marcos C, López C, Calleja JL, Fernández I, García-Samaniego J, Forns X, Buti M, Lens S.** Characterizing hepatitis delta in Spain and the gaps in its management. Gastroent Hepat-Barc. 2025; 48(2): 502222. Article. IF: 2.0; Q3
- **Virseda-Berdices A, Martín-Escolano R, Berenguer J, González-García J, Brochado-Kith O, Rojo D, Díez C, Hontañon V, Pérez-Latorre L, Ibañez-Samaniego L, Llop-Herrera E, Olveira A, Fernández-Rodríguez A, Barbas C, Resino S, Jiménez-Sousa MA, ESCORIAL Study Grp.** Metabolomic changes associated with the change in HVPG after DAAs therapy in HCV cirrhotic patients. Liver Int. 2025; 45(1): e16204. Article. IF: 6.2; Q1

Research projects

- **García-Samaniego Rey J.** Estudio epidemiológico y molecular de la infección por VHD en una gran área urbana de España. Optimización de la cascada de atención (PI22/00849). ISCIII. 2022-2027. Managment centre: FIBHULP
- **García-Samaniego Rey J.** Búsqueda activa de pacientes con hepatitis crónica viral (VHC Y VHD) no diagnosticada, en población general, desde los Centros de salud de la Comunidad de Madrid. Gilead Sciences S.L. 2022-2026. Managment centre: FIBHULP
- **García-Samaniego Rey J.** Study of the epidemiological situation and optimization of the cascade of care for patients with infection by the hepatitis delta virus (HDV). HDV DESCRIBE (EHD22PE02). Gilead Sciences S.L. 2023-2026. Managment centre: CIBER

Clinical trials

- **Olveira Martín A.** Ensayo de fase III multicéntrico, aleatorizado, doble ciego, comparativo con placebo, de 48 semanas de duración, para evaluar la eficacia y la seguridad de survodutide administrada por vía subcutánea en participantes con sobrepeso u obesidad y esteatohepatitis no alcohólica (ehna) presunta o confirmada.
  Type/Phase: III
  Sponsored by: Boehringer Ingelheim International Gmbh.
  Signature date: 10/10/2025
- **Olveira Martín A.** A randomised, double-blind, placebo-controlled, multicentre, phase iii trial evaluating long-term efficacy and safety of survodutide weekly injections in adult participants with noncirrhotic non-alcoholic steatohepatitis/metabolic associated steatohepatitis (nash/mash) and (f2) - (f3) stage of liver fibrosis.
  Type/Phase: IIIa
  Sponsored by: Boehringer Ingelheim International Gmbh.
  Signature date: 23/09/2025
- **Olveira Martín A.** A phase III double-blind, randomised, placebo-controlled trial to evaluate liver-related clinical outcomes and safety of once weekly injected survodutide in participants with compensated nonalcoholic steatohepatitis/ metabolic dysfunction associated steatohepatitis (nash/mash) cirrhosis.
  Type/Phase: III
  Sponsored by: Boehringer Ingelheim International Gmbh.
  Signature date: 16/09/2025
- **Olveira Martín A.** Characterization of pfic-related genes in adult patients with idiopathic ecurrent and chronic cholestasis in spain-regenic.
  Type/Phase: No EPA
  Sponsored by: Ipsen Pharma, S. A..
  Signature date: 12/11/2025
- **Olveira Martín A.** A phase IIIb randomised, parallel-group, double-blind, placebo-controlled, two-arm study to evaluate the effect of elafibranor 80 mg on normalisation of alkaline phosphatase in adult participants with primary biliary cholangitis (pbc) and inadequate response or intolerance to ursodeoxycholic acid.
  Type/Phase: IIIb
  Sponsored by: Ipsen Bioscience, Inc.
  Signature date: 18/06/2025
- **Olveira Martín A.** Estudio de fase 2a, aleatorizado, doble ciego y controlado con placebo para evaluar la eficacia y la seguridad de efinopegdutida (mk-6024) en adultos con cirrosis compensada secundaria a esteatohepatitis asociada a disfunción metabólica.
  Type/Phase: IIa
  Sponsored by: Merck Sharp & Dohme Llc.
  Signature date: 13/06/2025
- **Olveira Martín A.** A phase 3 randomized, open-label study to evaluate the efficacy and safety of tobevibart+elebsiran combination therapy in participants with chronic hdv infection not virologically suppressed with bulevirtide (eclipse 2).
  Type/Phase: III
  Sponsored by: Vir Biotechnology.
  Signature date: 19/09/2025
- **Olveira Martín A.** A phase 2b randomized, open-label study to evaluate the efficacy and safety of tobevibart+elebsiran combination therapy versus bulevirtide in participants with chronic hdv infection (eclipse 3).
  Type/Phase: IIb
  Sponsored by: Vir Biotechnology.
  Signature date: 17/10/2025
- **García Samaniego J .** Estudio de fase I/II abierto y multicéntrico para evaluar la seguridad, la tolerabilidad y la eficacia de los macrófagos autólogos de rtx001 en participantes con cirrosis hepática que presentan descompensación hepática (emerald).
  Type/Phase: II
  Sponsored by: Resolution Therapeutics Ltd.
  Signature date: 16/04/2025

Patents and trademarks

- **Castán P, Gil-García AI, Madejón A, Sainz-Martínez E, Montoya JJ, Ouahid Younes, inventors; MIRNAX BIOSENS S.**L., assignee. Bivalent reverse primers Aplication number (EPO): 20382336.4-1118. 2020 April 24.
- **Madejón A; inventor; Agile Life Sciences LTD, assignee.** Kit and methods Aplication number: GB202010372.A. 2020 July 6.

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