



New insights about organoids as model of study for breast cancer research

Ignacio U. Macías-Paz, Alejandro Rivera-Arenas, Elizabeth Reyna-Beltrán, and Alejandra Tavera-Tapia*

Dr. Alberto Romo Caballero's School of Medicine, Research Division, Universidad Autónoma de Tamaulipas, Tampico, Tamps., Mexico

Supplementary Material

Supplementary Table 1. Current clinical trials considering BC organoids models

Number of clinical trial	Status	Title/aim*	Interventions and organoid application	Study type	Enrollment	Country	Study start-study completion	Main finding
NCT03544047	Unknown	Drug sensitivity verification or prediction of therapy for BC by patient derived organoid model	To evaluate the consistency and accuracy of patient-derived organoid model of BC to predict the clinical efficacy of the drug paclitaxel	Interventional	50 F	China	January 2019-July 2020	NR
NCT02732860	Recruiting	Personalized patient-derived xenograft (pPDX) modeling to test drug response in matching host (REFLECT)	Molecular profiling and <i>in vivo</i> drug testing in pPDX and organoid cultures. Study includes triple-negative BC and other types of cancer as ovarian and colorectal	Observational	120 F/M	Canada	December 2015-November 2023	NR
NCT04450706	Recruiting	Precision oncology for metastatic BC	Clinically actionable outcomes identified by the use of organoids and drug screening in HER2 negative patients	Interventional	15 F/M	USA	February 2021-August 2025	NR
NCT03925233	Unknown	BC treatment based on organ-like culture	Establish a drug sensitivity test method by evaluating several drugs: trastuzumab hydrochloride, epirubicin hydrochloride, fluorouracil, paclitaxel, gemcitabine, cisplatin, recombinant human endostatin, pirarubicin, pyrrolidine, and other in BCO	Observational	300 F	China	January 2019-December 2021	NR
NCT04727632	Recruiting	Concordance between positive fluoroestradiol-PET/CT scan and response to hormonal therapies from drug profiling results using patient-derived organoid models	¹⁸ F]Fluoroestradiol (FES) PET/CT in estrogen receptor positive BC patients	Interventional	6 F/M	USA	March 2021-April 2025	NR
NCT04703244	Recruiting	Generate patient-derived xenografts (PDX) and organoids from BC patients with residual disease after neoadjuvant therapy	Chemotherapy or endocrine therapy for BC	Observational	100 F/M	USA	January 2021-January 2042	NR
NCT04504747	Not yet recruiting	Real-time molecular analysis of BC receiving neoadjuvant chemotherapy (NAC)	Establish patient derived organoids exposed to NAC	Observational	150 F	France	January 2021-January 2030	NR
NCT03896958	Recruiting	Enable best in class functional precision testing of a patient's tumor tissue to help guide optimal therapy (PIONEER initiative)	Organoid drug screening approaches in addition to traditional genomic profiling. This study includes several types of cancer including BC	Observational	1000 F/M	USA	March 2019-March 2024	NR
NCT04281355	Withdrawn	Individualized locoregional treatment of initially biopsy proven node-positive BC after primary systemic therapy	Drug tests in whole-tumor organoid cultures, algorithm-based digital image analysis, and gene expression analysis to improve response prediction, facilitate tailoring of pre-operative systematic therapy, and increase eradication rates.	Interventional	0	Sweden	January 2021-December 2029	NR
NCT01287468	Unknown	Investigate the tumor suppressive effect of anti-inflammatory phytomedicines on regulation of stromal immune cells and fibroblasts in BC	When potent and specific anti-tumor effects are detected, the investigators will extend the study to a three-dimensional collagen/Matrigel culture system for <i>ex vivo</i> study focusing on the stromal cell-mediated or -associated anti-tumor effects using organoid: tissue culture systems	Observational	415 F	Taiwan	June 2010-December 2014	NR
NCT04531696	Recruiting	Tissue donation program for metastatic BC patients or patients with a germline pathogenic variants (Leuven Program for Postmortem Tissue Donation to Enhance Research)	BC and hereditary diseases; unravel metastatic BC evolution, biology, heterogeneity, and treatment resistance including sub-studies with patient-derived organoids	Interventional	100 F/M	Belgium	November 2020-September 2035	NR
NCT04281641	Recruiting	Explore markers in early prediction of the efficacy of pre-operative pertuzumab plus trastuzumab (PH) combined with chemotherapy for early stage or locally advanced human epidermal growth factor receptor-2 (HER-2)-positive primary BC	HER2-positive BC, organoids will be used for drug sensitivity assay	Interventional	94 F/M	China	April 2020-April 2030	NR
NCT05177432	Recruiting	Quadratic phenotypic optimization platform (QPOP)	To investigate the feasibility of QPOP as a clinical decision support platform to identify	Interventional	26 F	Singapore	December 2021-December 2025	NR
NCT05007379	Not yet recruiting	Cohort study to determine the antitumor activity of new CAR macrophages in BC patients' derived organoids	To collect tumor samples to develop patients' derived organoids to test the antitumor activity of newly developed CAR macrophages.	Observational	100 F/M	France	September 2021-September 2023	NR
NCT04655573	Recruiting	Assess the feasibility of generating patient-derived micro-organospheres from patients with advanced BC to determine sensitivity to the most common forms of chemotherapy	Advanced BC (ER+, HER2-, ER+/HER2+, ER-/HER2+), derive micro-organospheres from biopsies from patients. After biopsy, treatment will be personalized based in the micro-organospheres	Observational	15 F/M	USA	April 2022-October 2024	NR
NCT05134779	Recruiting	Deconvoluting interactions between genes, the cancer environment, and the immune system to develop therapies	Designed to build a live tissue biobank of patient-derived tumor organoids (PDOs) derived from tumor at surgery, preceded or not by neoadjuvant therapy (NAT), and at recurrence/metastasis in specifically triple negative BC patients	Observational	400 F	USA	January 2022-December 2028	NR
NCT05404321	Not yet recruiting	Establishment of an <i>ex vivo</i> tumor collection of triple-negative BC to validate the interest of innovative therapies and the search for predictive biomarkers of response to treatment	Establishment of <i>ex vivo</i> BC organoid models (TNBC)	Observational	163 F	France	June 2022-December 2026	NR
NCT05317221	Not yet recruiting	Developing BC organoids	To develop a living biobank from prospective patient-derived BC tissue to explore genetic profile of the patients with the organoids and the patient biopsy. Cultivate BCOs to predict the treatment response to existing and novel combination treatments	Observational	60 F	Netherlands	May 2022-May 2028	NR
NCT05464082	Not yet recruiting	Functional precision oncology to predict, prevent, and treat	To develop patient derived models (PDMs), comprising patient-derived xenografts (PDXs) and organoids (PDO) and perform genomic	Interventional	80 F/M	USA	September 2022-September 2027	NR
NCT05429684	Recruiting	Precise therapy for refractory HER2-positive advanced BC	HER2-positive advanced BC. Evaluate several drugs as trastuzumab, pertuzumab, nab paclitaxel, pyrotinib, capecitabine, everolimus, CDK4/6 inhibitor, and anti-PD-1 monoclonal	Interventional	120 F	China	January 2021-February 2024	NR
NCT05381038	Not yet recruiting	Optimizing and personalizing azacitidine combination therapy for treating solid tumors QPOP and CURATE (artificial intelligence)	Includes BC and gastrointestinal cancer. Set the foundation to investigate the applicability of QPOP drug selection followed by CURATE AI-guided dose optimization of the selected azacitidine combination therapy. In the QPOP drug selection stage, participants will undergo a baseline biopsy for organoid generation.	Interventional	10 F/M	Singapore	June 2022-April 2027	NR
NCT04526587	Recruiting	Biomarkers and clinical features of metastatic BC in patients treated with CDK4/6 inhibitors	Stage IV BC, metastatic carcinoma, organoid, and patient-derived xenograft (PDX) models will be used to functionally assess the mechanisms occurring with resistance	Observational	300 F/M	USA	July 2020-July 2025	NR

F: female; M: male; BC: breast cancer; BCO: breast cancer organoid. *Summarized information has been included; NR: not reported. Information was retrieved from www.clinicaltrials.gov with information available until June 2022. Readers are encouraged to visit the webpage, as data are continually updated with novel advances.

***Correspondence:**
Alejandra Tavera-Tapia
E-mail: ataveratapia@gmail.com
2565-005X/© 2022 Sociedad Mexicana de Oncología. Published by Permanyer. This is an open access article under the terms of the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Date of reception: 18-08-2022
Date of acceptance: 21-09-2022
DOI: 10.24875/j.gamo.22000110

Available online: 28-11-2022
Gac Mex Oncol. 2022;21(4):135-142
www.gamo-smeo.com