

Studying the Safety and Determining the Optimal Dose of Novobiocin in Patients With Tumors That Have Alterations in DNA Repair Genes

NCT05687110

Status	RECRUITING
Phase	Phase 1
Sponsor	National Cancer Institute (NCI)
Enrollment	43 participants

Key Eligibility Criteria

Inclusion (23)

- Patients must have histologically confirmed malignancy that is metastatic or unresectable and for which standard curative or palliative measures do not exist or are no longer effective
- Patients must have histologically confirmed solid tumor with a known pathogenic mutation in BRCA1/2, PALB2, RAD51C, RAD51D, ATM, BARD1, BLM, BRIP1, CDK12, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCM, MRE11A, NBN (NBS1), RAD50 and RAD51B as confirmed by a Clinical Laboratory Improvement Amendments (CLIA)-certified method. Patients with alterations defined only by germline testing are eligible. Other qualifying HRD alterations may be considered if approved by the principal investigator and the Cancer Therapy Evaluation Program (CTEP) monitor
- Any number of prior therapy regimens is allowed
- Patients with cancers for which PARP inhibitors have been approved as standard-of-care must have received a PARP inhibitor prior to enrollment on this study. Other patients may be either PARP inhibitor-naïve (i.e., never have received a PARP inhibitor) or have disease that is PARP inhibitor-resistant (i.e., disease that has progressed radiologically based on Response Evaluation Criteria in Solid Tumors [RECIST] 1.1 while receiving any PARP inhibitor)
- Age \geq 18 years. Because no dosing or adverse event data are currently available on the use of novobiocin in patients $<$ 18 years of age, children are excluded from this study

... and 18 more (see full listing online)

Exclusion (12)

- Patients who have had chemotherapy or radiotherapy within 2 weeks (6 weeks for nitrosoureas or mitomycin C) prior to entering the study
- Patients who have not recovered from adverse events due to prior anti-cancer therapy (i.e., have residual toxicities $>$ grade 1) with the exception of alopecia
- Patients who are receiving any other investigational agents
- History of allergic reactions attributed to compounds of similar chemical or biologic composition to novobiocin
- Patients receiving any medications or substances that are strong inhibitors or inducers of CYP3A4/5 are ineligible. Patients receiving any medications or substances that are known to be substrates of breast cancer resistance protein (BCRP/ABCG2) and/or organic anion transporting polypeptides (OATP1B1, OATP1B3 and OATP2B1) and/or organic anion transporters (OAT1 and OAT3) within 14 days prior to the first dose of study drug are ineligible. Because the lists of these agents are constantly changing, it is important to regularly consult a frequently-updated medical reference. As part of the enrollment/informed consent procedures, the patient will be counseled on the risk of interactions with other agents, and what to do if new medications need to be prescribed or if the patient is considering a new over-the-counter medicine or herbal product

... and 7 more (see full listing online)

Locations (23 total)

City of Hope Comprehensive Cancer Center, Duarte, California, United States
UCI Health - Chao Family Comprehensive Cancer Center and Ambulatory Care, Irvine, California, United States
UC San Diego Moores Cancer Center, La Jolla, California, United States
... and 20 more locations

<https://clinicaltrials.gov/study/NCT05687110>

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