Immunotherapy With Chemotherapy and Chemoradiation for Advanced Squamous Cancer of Nasal Cavity / Paranasal Sinuses (I-NAPA)

NCT05027633

Status	RECRUITING
Phase	Phase 2
Sponsor	M.D. Anderson Cancer Center
Enrollment	35 participants

Plain Language Summary

This trial (I-NAPA) tests adding immunotherapy to the standard chemotherapy and radiation treatment for squamous cell cancer of the nasal cavity and sinuses that is at an advanced stage. The goal is to improve response rates and survival in a cancer type with limited treatment options.

You may be eligible if...
- You are 18 or older
- You have a new diagnosis of Stage II–IVb squamous cell carcinoma of the nasal cavity or paranasal sinuses
- You have not received any prior treatment for this cancer
- You are in generally good health and have measurable disease on imaging
- You are willing to use contraception during and after treatment

You may NOT be eligible if...
- You have received prior treatment for this cancer
- You have active autoimmune disease or certain other serious conditions
- You are pregnant or breastfeeding
- Your organ function does not meet requirements

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (11)

• Male/female participants who are at least 18 years of age on the day of signing informed consent with newly diagnosed, previously untreated, histologically and/or cytologically confirmed diagnosis of Stage II-IVb PNS SCC will be enrolled in this study.

• Male participants:

• A male participant must agree to use a contraception as detailed in Appendix 3 of this protocol during the treatment period and for at least 150 days after the last dose of study treatment and refrain from donating sperm during this period.

• Female participants:

• A female participant is eligible to participate if she is not pregnant (see Appendix 3), not breastfeeding, and at least one of the following conditions applies:

... and 6 more (see full listing online)

Exclusion (3)

• A WOCBP who has a positive urine pregnancy test within 72 hours prior to treatment (see Appendix 3). If the urine test is positive or cannot be confirmed as negative, a serum pregnancy test will be required.

• Has received prior therapy with an anti-PD-1, anti-PD-L1, or anti PD L2 agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (eg, CTLA-4, OX 40, CD137).

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• Patients must not have received prior systemic anti-cancer therapy including investigational agents or radiation therapy for PNS SCC but could have received treatment for prior cancers if greater than 2 years (refer to Item 8 for further details).

Locations (1 total)

M D Anderson Cancer Center, Houston, Texas, United States

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