UCSF Helen Diller Family Comprehensive Cancer Center

NT-I7 for the treatment of locally recurrent squamous cell carcinoma of head and neck undergoing salvage surgery

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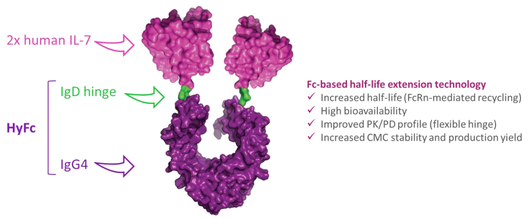
Background

- Immune checkpoint inhibitors (ICIs) have demonstrated clinical activity and survival benefit and were approved for care of advanced squamous cell carcinoma of head and neck (SCCHN) patients.
- However, the overall response rate to ICIs is around 10-15% and almost 40% of patients do not benefit from ICI treatment.
- Low absolute lymphocyte count (ALC) at baseline has been associated with a lower likelihood of receiving clinical benefit from ICIs in head and neck cancer. Importantly, the majority of head and neck cancer patients have received prior radiation therapy, which causes prolonged lymphopenia lasting for years.
- Interleukin-7 (IL-7) promotes the proliferation and survival of naïve and memory T cells, without inducing proliferation of immune suppressive regulatory T cells.
- NT-I7 (efineptakin alfa) is a fusion product of interleukin 7 (IL-7) with a human Fc domain, designed to prolong the half-life of IL-7.
- We hypothesize that administration of NT-I7 prior to salvage surgery will expand naïve and memory T cells in peripheral blood and increase tumor-infiltrating T cells.



Structure of NT-I7

Study Objectives

- Primary objective: To establish safety and feasibility of pre-operative administration of NT-I7 in locally recurrent SCCHN patients.
- Secondary objectives:

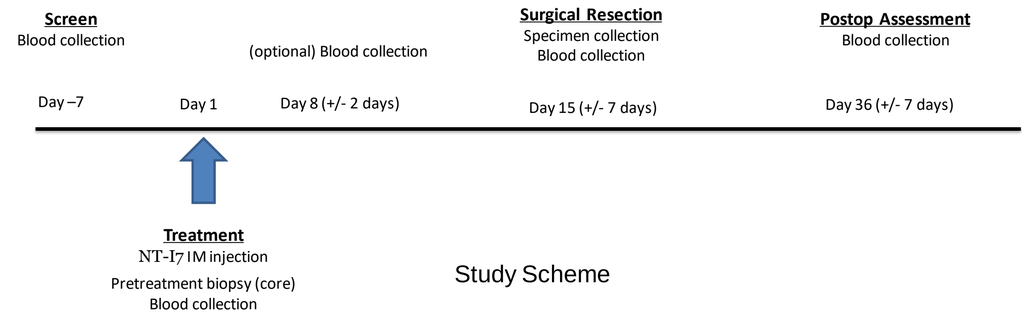
1) To determine the change in ALC in peripheral blood.
2) To examine changes in tumor-infiltrating lymphocytes in pre-operative biopsies and surgical specimens.
3) To evaluate changes in immune subsets in peripheral blood after a single administration of NT-I7.

Planned analysis

- Immune cell infiltration into the tumor and immune cells in peripheral blood before and after the NT-I7 treatment will be examined using mass cytometry by time of flight (CyTOF).
- Pre-treatment biopsy and post-treatment surgical specimen will be examined using Multiplexed Ion Beam Imaging (MIBI) .

Study design

- Patients with locally recurrent SCCHN undergoing curative intent salvage surgery will receive a single intramuscular injection of NT-I7.
- Pre-treatment biopsy and surgical specimen will be analyzed for tumor-infiltrating lymphocytes and immune subsets.
- ALCs and immune subsets in peripheral blood at baseline, at the time of surgery, and 5 weeks after the injection will be analyzed.



Study Scheme

Key eligibility criteria

1. Confirmed diagnosis of squamous cell carcinoma of oral cavity, oropharynx, hypopharynx or larynx with recurrent disease amenable for curative intent surgical resection
2. Age ≧ 18 years old
3. ECOG performance status ≦ 2
4. Had not received immune checkpoint inhibitor within 6 weeks prior to study entry, chemotherapy, radiotherapy or surgery within 4 weeks
5. No history of autoimmune disease, requiring active immune suppression

Progress

- The study was approved by UCSF IRB (#20-31673) and registered at clinicaltrials.gov (NCT04588038).
- The study has enrolled 1 out of 10 planned patients as of October 2022. The study was activated in February 2020, but the enrollment was delayed for COVID-19 crisis.

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