

Feasibility Study on the Effect of a Methionine-Reduced Diet on Serum Levels in Patients with Solid Tumors

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Methionine-Reduced Diet Trial

Background

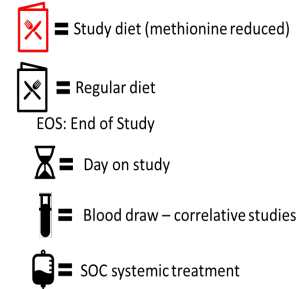
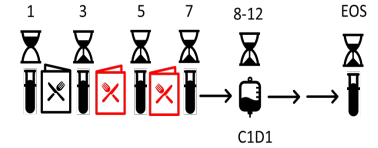
- Many solid tumors like carcinomas, sarcomas rely on high levels of methionine for growth.
- Methionine restriction has shown tumor growth inhibition and improved chemotherapy and radiation therapy response in animal models.

Trial Design

- **Type:** Single-center, open-label, Phase 0 feasibility study.
- **Objective:** Assess adherence to a methionine-reduced diet and its impact on plasma methionine levels in patients with solid tumors.

Study Objectives

- **Primary Endpoint:** Percentage of patients completing the prescribed diet.
- **Secondary Endpoint:** Adverse events (AE) by CTCAE v5.5, serum methionine levels, metabolomic and immunologic plasma markers levels.



Treatment Plan:

- Day 1-2: Regular diet with baseline blood draw on Day 1.
- Day 3-6: Methionine-reduced diet for 4 days.
- Day 3: Blood draw before starting diet.
- Day 5: Blood draw after 48 hours on diet.
- Day 7: Optional blood draw after 96 hours.
- Day 8-12: Standard of care (SOC) cancer treatment begins.
- Final Blood Draw: Between Days 21-28 after SOC initiation.

Thank You
