UC Irvine 趙 Chao Family Comprehensive Cancer Center

Feasibility Study on the Effect of a Methionine-Reduced Diet on Serum Levels in Patients with Solid Tumors (NCT 07628634)

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2026 Scientific Retreat
November 5, 2026

One of the most common questions we hear in clinic is:

"Doctor, should I be on any diet? Are there any foods I should avoid?"

Patients want to know if what they eat can help them fight cancer.

This question inspires an important scientific opportunity:

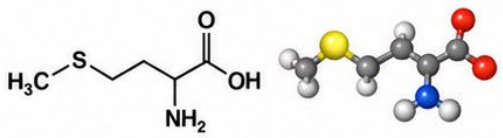
Can we target cancer metabolism through diet?

The scientific rationale: Why methionine?

1 Methionine: an essential amino acid

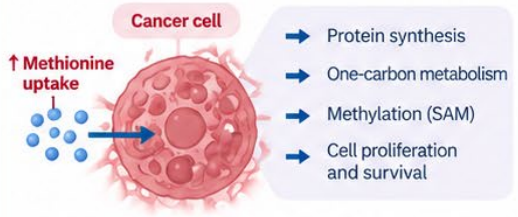
- Essential amino acid obtained from diet
- Involved in protein synthesis, one-carbon metabolism, and methylation (SAM)
- Required for numerous cellular processes

Methionine (Met)



2 Cancer has a metabolic vulnerability

- Many cancer cells exhibit increased dependence on exogenous methionine to support growth and proliferation.
- This phenomenon, often referred to as the Hoffman effect, provides a biological rationale for investigating methionine restriction as a potential therapeutic strategy.



Many cancer cells are highly dependent on exogenous methionine.

3 Diet may influence tumor metabolism

- Methionine availability influences the methionine cycle and downstream methylation reactions.
- Restricting dietary methionine may alter circulating methionine levels and metabolic pathways involved in tumor growth and cellular stress responses.
- This creates an opportunity to investigate whether a nutritional intervention can modulate cancer metabolism.



Methionine-reduced diet

Reduced tumor growth and/or enhanced **therapy response** (preclinical models)

4 Preclinical and human evidence supports the concept



- **Preclinical studies:** Methionine restriction enhanced therapeutic responses in chemetherapy-resistant, RAS-driven colorectal cancer models and radiation-resistant soft-tissue sarcoma models.



- **Human data:** A controlled dietary study demonstrated that methionine restriction produced systemic metabolic changes similar to those observed in preclinical models.

References: Maddocks et al. *Nature*. 2017; Gui et al. *Cancer Cell*. 2021; Solon-Biet et al. *Cell Metabolism*. 2019.

CLINICAL TRIAL

Turn a biological idea into a measurable clinical trial

Phase 0 • single site • single arm • 25 evaluable adults with solid tumors, including gliomas

01 Can they do it?



Diet completion and documented adherence

02 Does it change biology?



Serial blood methionine and exploratory metabolomics

03 Is it tolerable?



Adverse events, nutrition oversight and quality of life

Primary endpoint

Proportion completing the prescribed diet.

Secondary endpoint

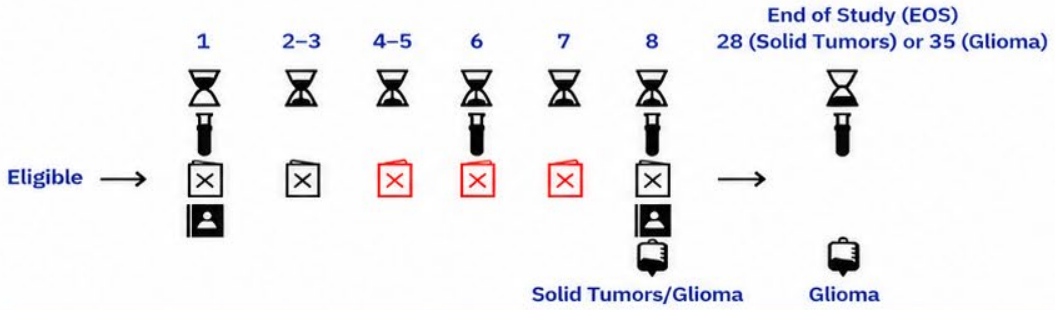
Adverse events (AE) by CTCAE v5.5, serum methionine levels, metabolomic and immunologic plasma markers levels.

CLINICAL TRIAL

Methionine-Reduced Diet Trial

A practical dietary intervention to improve cancer care.

Study design and timeline



= Day on study
= Plasma blood draw
= Regular diet
= Study diet (methionine reduced)
= Quality of Life (QoL) Questionnaire
= Standard of care cancer treatment initiation

Treatment plan

Day 1–3	Regular diet with baseline blood draw on Day 1.
Day 4–7	Methionine-reduced diet for 4 days.
Day 6	Blood draw after 48 hours on diet – the only extra blood draw.
Day 8	Blood draw after 96 hours (same time as SOC lab).
Day 9–12	Standard of care (SOC) cancer treatment begins.
Final blood draw	Between Days 21–28 after SOC initiation.

Inclusion criteria

- Diagnosis of metastatic, recurrent, or unresectable solid tumor (including Grade 2-3 glioma).
- ECOG 0-2.
- Adequate organ function, as determined by the investigator through review of standard labs.
- Able to receive systemic standard of care cancer therapy.

Exclusion criteria

- Uncontrolled or symptomatic brain metastases.
- Uncontrolled Diabetes.
- Significant Amino Acid/Metabolic Illnesses: including but not limited to: Severe liver disease, Inherited metabolic disorders (such as homocystinuria), Severe gastrointestinal disorders, such as active inflammatory bowel disease (IBD).
- Severe malnutrition or significant nutritional deficiencies per investigator judgement.

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Methionine-Restricted Diet: Examples and Sample Meals

Foods Allowed (Lower in Methionine)

Examples of commonly used foods in MR diet



Sample Breakfast

Low-methionine, balanced, and practical



- Oatmeal (cooked with water)
- Banana and blueberries
- Black coffee or tea (unsweetened)

Sample Dinner

Simple, plant-based, and satisfying



- White rice
- Stir-fried vegetables (e.g., broccoli, carrots, zucchini, bell peppers)
- Tofu
- Season with olive oil, garlic, herbs, spices

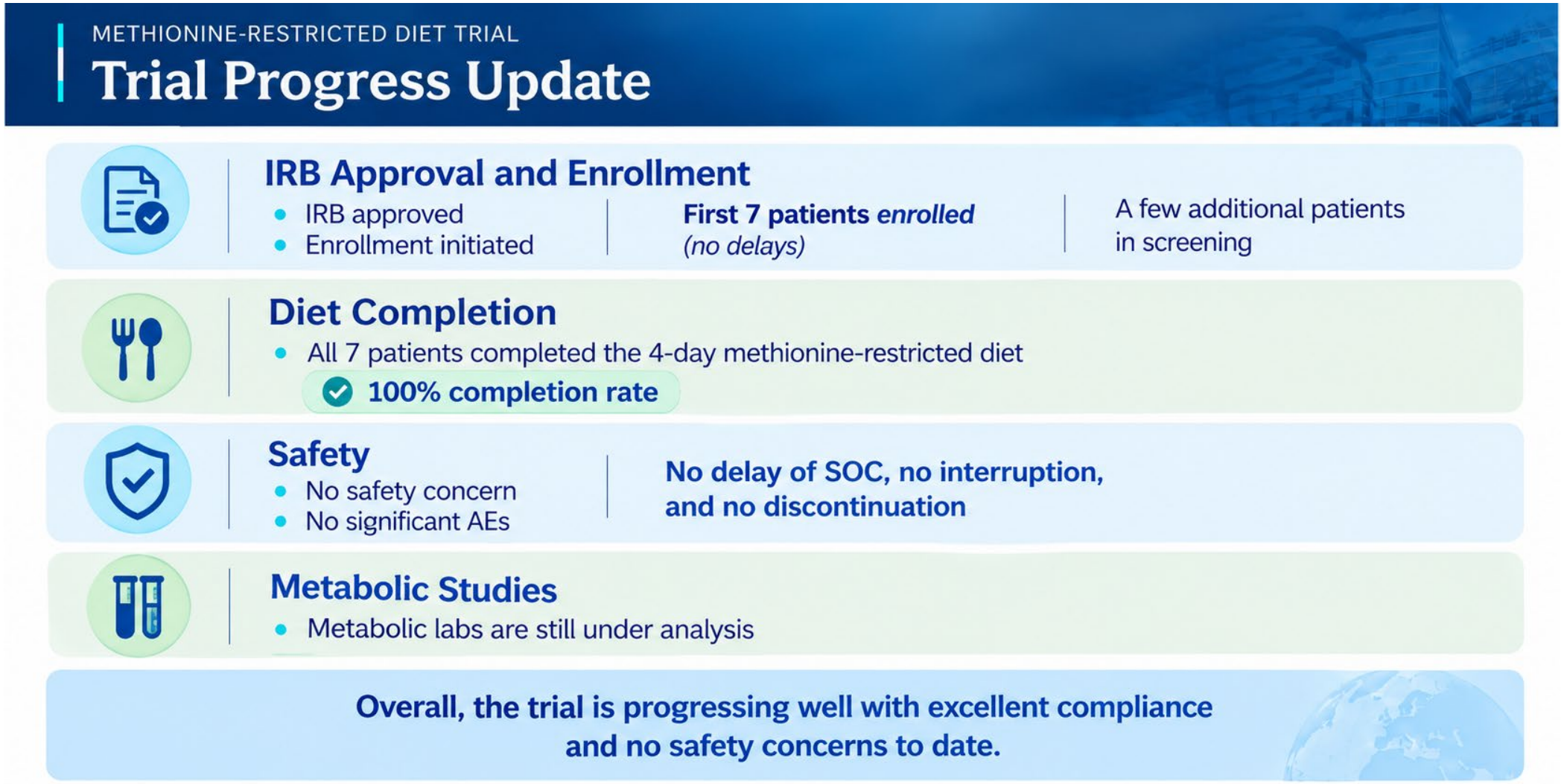
Foods to Limit or Avoid (Higher in Methionine)



Practical Tips

- Focus on plant-based foods and refined carbohydrates.
- Use herbs, spices, lemon, garlic, and olive oil for flavor.
- Choose low-protein protein alternatives (e.g., tofu).
- Avoid meat, fish, eggs, dairy, nuts, and legumes.
- Maintain adequate calorie intake and nutrition.

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Thank you!