

# INPLASY PROTOCOL

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submission:** Preliminary  
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**Conflicts of interest:**  
None declared.

## The clinical effect of an elemental diet during chemotherapy in patients with esophageal cancer: A meta-analysis

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**Review question / Objective:** P:esophageal cancer; I:elemental diet; C:without elemental diet; O:Adverse Events and nutritional status; S:Prospective and Randomized study.  
**Eligibility criteria:** The inclusion criteria were as follows: (1)Eligible patients with histologically or cytologically confirmed squamous cell carcinoma, adenosquamous cell carcinoma, or Siewert typel adenocarcinoma of the esophagus were enrolled by the study investigators. (2) Adults (18 years old or older); (3) schedule to undergo chemotherapy or chemoradiotherapy.(4)adequate hematologic, hepatic, renal and cardiac function. (5)agreement to participate (written informed consent).(6) studies reported with Adverse Events;(7) Prospective and Randomized study; and (8) when results from an study were reported and analyzed more than once, the primary data were included.The exclusion criteria were as follows: (1) not related to esophageal cancer;(2) reviews, meta-analysis, case reports, letters, or expert opinions; (3) single arm; (4) insufficient data; (5) experimental group did not receive elemental diet; (6) duplicates; (7) studies that enrolled patients younger than 18 years old or animals; and (8) not Prospective or not Randomized study.(9) presence of uncontrolled infection; the use of other nutritional supplements; poor control of diabetes or the use of insulin treatment.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 June 2022 and was last updated on 06 June 2022 (registration number INPLASY202260021).

### INTRODUCTION

**Review question / Objective:** P:esophageal cancer; I:elemental diet; C:without elemental diet; O:Adverse Events and

nutritional status; S:Prospective and Randomized study.

**Condition being studied:** The oral elemental diet comprises 18 different types of amino

acids as well as several other important elements and does not require digestion. As a result, including ED in the treatment regimen may aid in intestinal absorption by maintaining villi in the small intestine, thus reducing AEs and enhancing chemotherapy adherence.

## METHODS

**Participant or population:** (1) Eligible patients with histologically or cytologically confirmed squamous cell carcinoma, adenosquamous cell carcinoma, or Siewert type I adenocarcinoma of the esophagus were enrolled by the study investigators. (2) Adults (18 years old or older); (3) schedule to undergo chemotherapy or chemoradiotherapy. (4) adequate hematologic, hepatic, renal and cardiac function. (5) agreement to participate (written informed consent). (6) studies reported with Adverse Events. The inclusion criteria were as follows: (1) Eligible patients with histologically or cytologically confirmed squamous cell carcinoma, adenosquamous cell carcinoma, or Siewert type I adenocarcinoma of the esophagus were enrolled by the study investigators. (2) Adults (18 years old or older); (3) schedule to undergo chemotherapy or chemoradiotherapy. (4) adequate hematologic, hepatic, renal and cardiac function. (5) agreement to participate (written informed consent). (6) studies reported with Adverse Events; (7) Prospective and Randomized study; and (8) when results from an study were reported and analyzed more than once, the primary data were included. The exclusion criteria were as follows: (1) not related to esophageal cancer; (2) reviews, meta-analysis, case reports, letters, or expert opinions; (3) single arm; (4) insufficient data; (5) experimental group did not receive elemental diet; (6) duplicates; (7) studies that enrolled patients younger than 18 years old or animals; and (8) not Prospective or not Randomized study. (9) presence of uncontrolled infection; the use of other nutritional supplements; poor control of diabetes or the use of insulin treatment.

**Intervention:** Elemental diet.

**Comparator:** Without elemental diet.

**Study designs to be included:** Prospective and Randomized study.

**Eligibility criteria:** The inclusion criteria were as follows: (1) Eligible patients with histologically or cytologically confirmed squamous cell carcinoma, adenosquamous cell carcinoma, or Siewert type I adenocarcinoma of the esophagus were enrolled by the study investigators. (2) Adults (18 years old or older); (3) schedule to undergo chemotherapy or chemoradiotherapy. (4) adequate hematologic, hepatic, renal and cardiac function. (5) agreement to participate (written informed consent). (6) studies reported with Adverse Events; (7) Prospective and Randomized study; and (8) when results from an study were reported and analyzed more than once, the primary data were included. The exclusion criteria were as follows: (1) not related to esophageal cancer; (2) reviews, meta-analysis, case reports, letters, or expert opinions; (3) single arm; (4) insufficient data; (5) experimental group did not receive elemental diet; (6) duplicates; (7) studies that enrolled patients younger than 18 years old or animals; and (8) not Prospective or not Randomized study. (9) presence of uncontrolled infection; the use of other nutritional supplements; poor control of diabetes or the use of insulin treatment.

**Information sources:** Pubmed, Embase, web of science and the Cochrane Library.

**Main outcome(s):** Adverse Events and nutritional status.

**Quality assessment / Risk of bias analysis:** The risk of bias was assessed by the Cochrane Collaboration and was classified as "low", "unclear", or "high" in several areas.

**Strategy of data synthesis:** In this meta-analysis, heterogeneity was evaluated with

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I<sup>2</sup> statistics . An I<sup>2</sup> >50% implied significant heterogeneity .The significance level was set at 0.05, and tests were two-sided. Sensitivity analysis were performed where appropriate. All statistical analyses were carried out using Review Manager 5.4.1 and StataMP software.

**Subgroup analysis:** Grade of adverse events.

**Sensitivity analysis:** 1.My personal papers generally choose the random model, because the random model is relatively conservative and makes the results more safe 2.excluded references on a case—by—case basis.

**Language:** English.

**Country(ies) involved:** China.

**Keywords:** elemental diet, esophagus cancer.

**Contributions of each author:**

Author 1 - Lan Haoning.

Author 2 - Zhang Huiyun.

Author 3 - Yao Jiannan.