

A multicentre randomised controlled trial of nutritional intervention for patients with weight loss who are undergoing chemotherapy for gastrointestinal (GI) Malignancy, Non Small Cell Lung cancer (NSCL) or Mesothelioma

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 12/06/2015	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-nutrition-supplements-and-dietary-advice-for-people-due-to-have-chemotherapy-for-advanced-cancer>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

CCR1999

Study information

Scientific Title

A multicentre randomised controlled trial of nutritional intervention for patients with weight loss who are undergoing chemotherapy for gastrointestinal (GI) Malignancy, Non Small Cell Lung cancer (NSCL) or Mesothelioma

Acronym

The NUT Study

Study objectives

Nutritional intervention in people with metastatic gastrointestinal malignancy is associated with survival benefit

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cancer: Gastrointestinal

Interventions

1. Dietary advice to increase food intake by 600 calories
2. Dietary advice to increase intake by 600 calories plus oral supplement drink providing 588 calories plus mineral and vitamin supplement
3. Supplement drink plus vitamin and mineral supplement but no dietary advice
4. No dietary advice or supplements

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Survival benefit related to nutritional intervention. Dietary advice to improve nutritional intake results in weight gain.

Key secondary outcome(s)

Any additional benefits when nutritional supplements are given with dietary advice.

Completion date

01/12/2007

Eligibility**Key inclusion criteria**

Patients who have agreed to undergo chemotherapy for histologically proven metastatic or locally advanced tumours in the gastrointestinal tract who are fit for chemotherapy and have weight loss defined by at least one of the following criteria: Body Mass Index $<20 \text{ kg/m}^2$, weight loss of 55 or more over 3 months or greater, body weight of 5% or more below ideal body weight.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Clinical condition precluding oral nutrition, unable to tolerate milk, being considered for immediate enteral or parenteral nutrition.

Date of first enrolment

01/11/2002

Date of final enrolment

19/10/2006

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Royal Marsden NHS Foundation Trust
London
United Kingdom
SW10 9NH

Sponsor information

Organisation

Royal Marsden NHS Foundation Trust (UK)

ROR

<https://ror.org/0008wzh48>

Funder(s)

Funder type

Charity

Funder Name

Henry Smith Foundation and Dr J Andreyev's Research Fund (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	1. results	01/05/2008		Yes	No
Results article	results	01/10/2011		Yes	No