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NUtritional Support in Patients with newly diagnosed oEsophageal Cancer

Submission date	Recruitment status	[ ] Prospectively registered
11/05/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/06/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/06/2011	Cancer	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Onc. 2.C/C

Study information

Scientific Title
NUtritional Support in Patients with newly diagnosed oEsophageal Cancer: a randomised, double blind, controlled clinical trial

Acronym
NUSPEC

Study objectives
The active sip feed is expected to beneficially change pre-treatment immune function in patients with newly diagnosed cancer of the oesophagus compared to routine nutritional support.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of the Erasmus (Medisch Ethische Toetsings Commissie Erasmus MC), Rotterdam, Netherlands approved on 14th June 2007, reference number: MEC-2007-109

Primary study design
Interventional

Study design
Randomised double blind controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Oesophageal cancer

Interventions
Duration of intervention: 4 weeks pre-treatment

Active products: Nutritionally complete oral supplement, high in protein and leucine and enriched with fish oil, specific oligosaccharides and a balanced mix of vitamins, minerals and trace elements.

Active products:
1. Body weight loss in past 3 months is 0 to < 5% or weight gain and dysphagia score is 0 or 1: Active sip feed (2 x 200 mL daily)
2. Body weight loss in past 3 months 5% or more and/or dysphagia score 2 or 3 and/or patients using/prescribed sip feed in the last 4 weeks: Active sip feed (at least 2 x 200 mL daily)

Control products: The control product is either a non-caloric placebo product or an iso-caloric standard nutritional product, both without fish oil enrichment or specific oligosaccharides.

Routine Care (Control products):
1. Body weight loss in past 3 months is 0 to < 5% or weight gain and dysphagia score 0 or 1: Placebo sip feed (2 x 200 mL daily)
2. Body weight loss in past 3 months 5% or more and/or dysphagia score 2 or 3 and/or patients using/prescribed sip feed in the last 4 weeks: iso-caloric control sip feed (at least 2 x 200 mL daily)

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Nutritional feeds

Primary outcome(s)
To assess the effects of the Active sip feed on pre-treatment immune function in patients with newly diagnosed cancer of the oesophagus and to compare this with the effects of routine nutritional support.

Immune function was measured by the ex vivo production of Th1/Th2 cytokines in ConA stimulated peripheral blood mononuclear cells (PBMC) and production of inflammatory cytokines and prostaglandin E2 (PGE2) in lipopolysaccharides (LPS)-stimulated PBMC, both at visit 1 and visit 3. Cytokines were measured by Bio-Plex assay and PGE2 by enzyme immunoassay (EIA).

Key secondary outcome(s)
1. To assess the effects of the Active sip feed on pre-treatment nutritional status in patients with newly diagnosed cancer of the oesophagus and to compare this with the effects of routine nutritional support.
2. To obtain exploratory information on immune function and nutritional status post-surgery
3. To obtain data on immune and nutritional parameters in healthy volunteers to allow for adequate interpretation of the data from patients

Completion date
01/02/2009

Eligibility

Key inclusion criteria
Patients:
1. Newly diagnosed with carcinoma of the oesophagus or gastro-oesophageal junction (Siewert-Stein classification type I - III)
2. Age more than or equal to 18 years
3. Written informed consent

Reference group (were included for baseline comparisons, no intervention in these subjects):
1. Age and sex-matched with the Dutch oesophagus cancer population
2. Written informed consent
3. Body mass index (BMI) 18.5-30 kg/m2

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 Years

Sex
All

Key exclusion criteria
Patients:
1. Life expectancy < 3 months
2. Planned start of cancer treatment within 3 weeks
3. Eastern Cooperative Oncology Group (ECOG) performance status > 2
4. Any oesophagus related surgery after diagnosis before inclusion
5. Chemo- and/or radiotherapy in the past 5 years
6. Altered immune function [e.g. caused by major active infection, autoimmune disease, active allergy, rheumatoid arthritis, inflammatory bowel diseases, multiple sclerosis, or by use of medication such as immunosuppressive drugs, immunomodulators, or corticosteroids (unless not considered to be systemically available)]
7. Dysphagia score of 4 using the dysphagia scoring system
8. Dependence on tube feed or parenteral nutrition in the last 4 weeks
9. Use of fish oil containing supplements during the last 4 weeks
10. Intolerance or allergy to dairy, fish, or other ingredients of the study products
11. Dependency on fibre free diet
12. If pre-menopausal female: pregnant or lactating
13. Dementia or altered mental status that would prohibit the understanding and giving of informed consent
14. Any other medical condition that may interfere with the safety of the patient or the outcome parameters, in the investigators judgment.
15. Investigators uncertainty about the willingness or ability of the patient to comply with the protocol requirements (e.g. alcohol abuse)

Reference group (were included for baseline comparisons, no intervention in these subjects):
1. Significant involuntary weight loss in the past year
2. Smoking (defined as currently smoking or quit less than or equal to 6 months ago)
3. Acute or chronic disease
4. Altered immune function [e.g. caused by major active infection, autoimmune disease, active allergy, rheumatoid arthritis, inflammatory bowel diseases, multiple sclerosis, or by use of medication such as immunosuppressive drugs, immunomodulators, or corticosteroids (unless not considered to be systemically available)]
5. If pre-menopausal female: pregnant or lactating
6. Any other condition that may interfere with the definition healthy volunteer according to the investigators judgement

Date of first enrolment
01/08/2007

Date of final enrolment
01/02/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
S-Gravendijkwal 230
Rotterdam
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Sponsor information

Organisation
Danone Research (Netherlands)

ROR
https://ror.org/01c5aqt35

Funder(s)

Funder type
Industry

Funder Name
Danone Research (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration