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Hypermetabolism, cachexia and survival in cancer

Submission date	Recruitment status	[_] Prospectively registered
30/08/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/09/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/11/2020	Cancer	

Plain English summary of protocol

Background and study aims
Cancer and treatment for cancer can affect a person's appetite and how they digest, absorb and use food. This can lead to malnutrition. Cancer-related malnutrition can make a person feel tired, weak and not well enough to be treated for the disease and it is a major cause of death in cancer patients.
The role of energy metabolism (that is, the process of getting and using energy from food) in cancer malnutrition remains unclear. Resting energy expenditure (REE) is the amount of energy that is used over a 24 hour period expended in 24 hours by the body at rest. The objective of the study is to determine the relationship between cancer malnutrition, cancer survival and energy expenditure.

Who can participate?
Cancer patients over the age of 18 and being treated at the Cochin Teaching Hospital.

What does the study involve?
All participants have their REE measured by a method called indirect calorimetry before they start chemotherapy treatment. This involves by measuring the amount of carbon dioxide a person breathes out or the amount of oxygen they breathe in. For this study, each participant is asked to wear a nose clip and mouthpiece system which is connected to a xygen analyser. The REE is measured after the participants have not eaten for 12 hours (12-hour fasting) and took 15 minutes. Each participant was also assessed for weight loss, how much energy they take in (in the form of food eaten), evidence of body inflammation and malnutrition (by analyzing for certain proteins in the blood) and overall general wellbeing. Overall survival data is also collected.

What are the possible benefits and risks of participating?
Participating in this study has no influence on cancer treatment or care. The data collected are analysed with statistical specific test to explore the impact of resting energy expenditure on cancer malnutrition and survival. A better knowledge of cancer malnutrition could improve both its management and patient's quality of life.

Where is the study run from?
Cochin Teaching Hospital, Paris (France)

When is the study starting and how long is it expected to run for?
June 2012 to May 2014

Who is funding the study?
Cochin Teaching Hospital, Paris (France)

Who is the main contact?
1. Dr Clara Vazeille
2. Professor François Goldwasser
3. Dr Anne Jouinot

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
041281622

Study information

Scientific Title
Relationship between hypermetabolism, cachexia and survival in cancer patients: a prospective study in 390 cancer patients prior to chemotherapy initiation.

Study objectives
Hypermetabolism is an important determinant of cancer cachexia and thereby have an influence on overall survival

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cochin institutional review board and local ethics committee, 30/04/2012, ref: CLEC N° 041281622.

Study design
Prospective observational cross-sectional and longitudinal study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Hypermetabolism, malnutrition and survival in cancer patients.

Interventions
This study involved the measurement of resting energy expenditure by indirect calorimetry using with nose clip and mouthpiece system connected to an oxygen analyser (Fitmate ®, Cosmed, Brignais, France). The measure was performed after a 12-hour fasting and lasted 15 minutes in a resting patient.

Participants were evaluated before systemic treatment initiation including adjuvant chemotherapy. The following parameters were recorded:
1. Weight loss

2. WHO Performance status (PS)
3. C-reactive protein (CRP)
4. Albumin
5. Nutritional Risk index (NRI) =1.519× albumin +41.7×(current weight/usual weight), daily energy intake (DEI), resting energy expenditure (REE) and energy balance

Median follow-up was 15.5 month.

Intervention Type
Other

Primary outcome(s)
Comparison of weight loss in hypermetabolic patients to weight loss in normometabolic patients.

1. Weight loss is calculated as the percentage of weight lost from healthy condition to the date of recruitment: (recruitment weight-healthy weight)*100/healthy weight.
2. Metabolism is determined by measuring the resting energy expenditure (REE) by indirect calorimetry with nose clip and mouthpiece system connected to an oxygen analyser (Fitmate ®, Cosmed, Brignais, France). Measured REE is compared to calculated REE using revised Harris and Benedict equation: Hm is defined as having measured REE ≥110% of calculated REE, Nm 90 to 110% of calculated REE and hypometabolic patients <90%.

All outcome data was measured on the day of indirect calorimetry .

Key secondary outcome(s))
Comparison between hypermetabolic and normometabolic patients for:
1. Patient general well-being and activities of daily life, assessed using the WHO performance status
2. C-reactive protein levels, measured using liquid turbidimetry
3. Albumin levels, measured using nephelemetry
4. Nutritional Risk index (NRI)=1.519× albumin +41.7×(current weight/usual weight), daily energy intake , energy balance (=daily energy intakes-Resting Energy expenditure), fat-free mass and overall survival
5. Energy intake, estimated for each patient by an experienced dietician using the 24-hour recall method
6. Fat free mass, measured by evaluation of skeletal muscle tissue cross-sectional area at the third lumbar vertebra on Computed tomography (when images available). Analyses were made with the ImageJ software v1.42q
7. Overall survival, defined as the time between inclusion and death

All outcome data were collected on the day of indirect calorimetry except overall survival (median follow-up 15.5 month).

Completion date
01/05/2014

Eligibility

Key inclusion criteria

Cancer outpatients and inpatients over 18 years. Patients were recruited as they benefit from a routinely evaluation before systemic treatment initiation. We included all cancer patients, any stage, evaluated before systemic treatment initiation including adjuvant chemotherapy.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
390

Key exclusion criteria
1. Patients who were not able to undergo indirect calorimetry (claustrophobia, oxygen therapy, flat nose bridge)
2. Patients who underwent anti-cancer therapy within the previous 30 days.

Date of first enrolment
04/06/2012

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
France

Study participating centre
Medical Oncology, Cochin Teaching Hospital, AP-HP, Paris Descartes University
27 rue du Faubourg Saint Jacques
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Sponsor information

Organisation
Medical Oncology, Cochin Teaching Hospital, AP-HP, Paris Descartes University

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Cochin Teaching Hospital, Paris (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2017	27/11/2020	Yes	No