Marie Curie Research Grants Scheme

Care and support through terminal illness | Marie Curie

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The MENAC Trial: A randomised, open-label trial of a **M**ultimodal Intervention (**E**xercise, **N**utrition and **A**nti-inflammatory Medication) plus standard care versus standard care alone, to prevent/attenuate **C**achexia in patients with advanced cancer undergoing chemotherapy.

Duration: 30 months
Start Date: 01/09/2016
Budget: £157,377.22

Abstract

Background

The MENAC trial is the first phase III clinical trial of a multimodal cachexia intervention in patients with advanced cancer (lung or pancreatic) undergoing palliative chemotherapy. Cancer cachexia is characterized by weight loss, muscle wasting, anorexia and fatigue. It is prevalent in pancreatic and lung cancer where mean survival is less than one year. There is no standard of care for cachexia.

Through our increased understanding of cachexia pathophysiology (muscle wasting, reduced physical activity, negative energy/protein balance, systemic inflammation), there is now a sound argument that cachexia may be reversed through multimodal intervention (comprising oral nutritional supplements (ONS) and counselling, exercise programme omega-3 fatty-acids and ibuprofen) initiated at the start of chemotherapy may be beneficial. Our pilot study (preMENAC Study NCT01419145) has informed this proposal and shown the intervention (including basic exercise) is feasible.

Building on these exciting preliminary findings, we are now undertaking a phase III trial, the MENAC trial, to fully explore if a multimodal cachexia intervention is beneficial. This international trial is being led by researchers from the University of Edinburgh and the European Palliative Care Research Centre (Norway) and is being conducted primarily in the UK, Scandinavia and Canada. Approximately 70% of trial activity will take place in the UK and this is being funded through a unique collaboration between the Rising Tide Foundation for Clinical Cancer Research (74%), Marie Curie (19%) and Pancreatic Cancer UK (7%). In particular Marie Curie and Pancreatic Cancer UK are supporting trial infrastructure and additional research nurse support.

Research Question

Does a multimodal intervention improve nutritional status, physical function, quality of life and oncological outcomes in patients with lung or pancreatic cancer?

Methods

Design: An international, open-label, randomized phase III study of a multimodal cachexia intervention versus standard cancer care.

Participants

Patients with incurable lung or pancreatic cancer starting anti-cancer therapy.

Intervention
Multimodal intervention (Oral nutritional supplements, ibuprofen and a tailored exercise programme).

Comparator
Standard cancer care - offered the intervention after 6 weeks (endpoint) to limit contamination.

Outcomes
Assessed 6 weeks from baseline.
Primary outcome: the effect of the intervention on weight.
Secondary outcomes: physical function, muscle mass and quality of life (EORTC QLQ-C30).
Patients will have follow up at 12 weeks. An evaluation process will be incorporated.