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Application of adenosine-5-triphosphate infusions in palliative home care

Submission date 14/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/11/2006	**Overall study status** Completed	
Last Edited 06/11/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Application of adenosine-5-triphosphate infusions in palliative home care

Study objectives
1. Does Adenosine-5-Triphosphate (ATP) administration to terminal cancer patients improve the quality of life, in terms of functional status and health complaints such as fatigue, exhaustion and weight loss?
2. Does ATP infusion relieve family caregiver burden and reduce use of professional health care services?
3. Is application of ATP infusions in a home care setting feasible for terminal cancer patients?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee of the Academic Hospital Maastricht and Maastricht University, date of approval: 4 July 2001 (ref. number: METC 01-092).

Study design
Open-labelled, randomised controlled trial with two parallel groups

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Cancer patients in the end stage of disease

Interventions
Control group:
Usual care and additional home visits by a dietician

Intervention group:
Usual care, additional home visits by a dietician and ATP infusions (eight to 12 hour infusion every week during the study period of eight weeks)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Adenosine-5-triphosphate (ATP)

Primary outcome(s)

1. Quality of life
2. Fatigue
3. Physical restriction

Key secondary outcome(s))
1. Appetite
2. Nutritional intake
3. Anthropometric measurements
4. Muscle strength
5. Caregiver burden

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Cancer patients for whom no systemic treatment is available, or medical treatment options are restricted to palliative/supportive care
2. Life expectancy of less than six months
3. The diagnosis cancer must have been confirmed histologically or cytologically
4. World Health Organisation (WHO) performance status classification in cancer one or two
5. Presence of at least one of the following complaints:
a. fatigue
b. weight loss over 5% over last six months
c. anorexia

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
1. Symptomatic angina pectoris
2. Symptomatic heart failure
3. Any form of AtrioVentricular (AV)-block (assessed by Electrocardiogram [ECG])
4. Cognitive dysfunction or other disease obstructing an adequate follow up
5. Life expectancy of less than four weeks
6. Concurrent palliative chemotherapy

Date of first enrolment
01/01/2002

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
University Maastricht
Maastricht
Netherlands
6200 MD

Sponsor information

Organisation
University Maastricht (The Netherlands)

ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
University/education

Funder Name
University Maastricht (The Netherlands)

Funder Name
Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location
Netherlands

Funder Name
Stichting NFK (The Netherlands)

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?
Protocol article	Study protocol:	08/01/2007		Yes	No