

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

<b>Submission date</b> 14/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 10/11/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/11/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

## 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?
<a href="#">Protocol article</a>	Study protocol:	08/01/2007		Yes	No