

# Randomised Phase I/II Study with Ghrelin versus Placebo for patients with cancer-related Anorexia/Cachexia

<b>Submission date</b> 08/07/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/01/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
SG 242/03

# Study information

## Scientific Title

Randomised Phase I/II Study with Ghrelin versus Placebo for patients with cancer-related Anorexia/Cachexia

## Acronym

Ghrelin

## Study objectives

Ghrelin is a safe new treatment option in patients with advanced cancer and involuntary loss of weight and appetite.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Cancer-related anorexia/cachexia

## Interventions

Ghrelin intravenous versus placebo.

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Ghrelin

**Primary outcome measure**

1. Safety of parenteral Ghrelin administered in patients with advanced cancer suffering from the anorexia/cachexia syndrome
2. Qualitative and quantitative toxicities

**Secondary outcome measures**

Symptomatic effect of parenteral Ghrelin on appetite, other anorexia/cachexia related symptoms, and health-related quality-of-life (HRQOL) in patients with advanced cancer suffering from the anorexia/cachexia syndrome.

Effect of parenteral Ghrelin on nutritional intake and food preferences.

**Overall study start date**

01/03/2004

**Completion date**

01/09/2005

## **Eligibility**

**Key inclusion criteria**

Patients with any type of advanced, incurable cancer, not requiring new or not being on antineoplastic treatment during the study period, with weight loss (>2% 2 months or >5% 6 months) and anorexia (VAS >3) will be eligible.

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

20

**Total final enrolment**

21

**Key exclusion criteria**

Severe structural barriers in the upper gastrointestinal tract, bowel obstruction.

**Date of first enrolment**

01/03/2004

**Date of final enrolment**

01/09/2005

# Locations

## Countries of recruitment

Switzerland

## Study participating centre

### Oncology and Palliative Medicine

St.Gallen

Switzerland

9007

# Sponsor information

## Organisation

Kantonsspital St. Gallen [St Gallen Cantonal Hospital]

## Sponsor details

Oncology/Haematology Dept

Internal Medicine

Cantonal Hospital

Rorschacherstrasse

St.Gallen

Switzerland

9007

## Sponsor type

Hospital/treatment centre

## ROR

<https://ror.org/00gpmb873>

# Funder(s)

## Funder type

Industry

## Funder Name

Pilot Grant Swiss Institute for Applied Cancer REsearch; REsearch Grant OncoSuisse; Cancer League Eastern Switzerland; ALTANA Prize; Gastrotech DK

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## 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="#">Results article</a>	results	29/01/2008	07/01/2020	Yes	No