ISRCTN26185223 https://doi.org/10.1186/ISRCTN26185223

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

| | | |
|---|---|---|
| **Submission date**<br>08/07/2005 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>12/09/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>07/01/2020 | **Condition category**<br>Cancer | |

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

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Florian Strasser

**Contact details**
Oncology and Palliative Medicine
Section Oncology/Haematology
Dept. Internal Medicine
Cantonal Hospital
St.Gallen
Switzerland
9007

## Additional identifiers

**Protocol serial number**
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

## Primary study design
Interventional

## Study design
Randomised controlled trial

## Study type(s)
Treatment

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

## Key secondary outcome(s)

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.

### 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

### Healthy volunteers allowed
No

### Age group
Not Specified

### Sex
Not Specified

### 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]

**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

## 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? |
|---|---|---|---|---|---|
| Results article | results | 29/01/2008 | 07/01/2020 | Yes | No |