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

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

Study design

Randomised controlled trial

Primary study design

Interventional

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

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