Effect of lenalidomide (Revlimid) in solid tumour patients with inflammatory cancer cachexia syndrome on lean body mass and muscle strength: A multicenter, proof-of-concept study of fixed dose or CRP-response-guided dose of lenalidomide in relation to new standard basic cachexia management (receiving placebo) EKSG 09/40; CTU-11006

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Die Studie zielt darauf ab herauszufinden, ob Lenalidomid (Revlimid®), einmal täglich als Kapsel eingenommen auf nüchternen Magen, eine therapeutische Bedeutung beim tumorbedingten Gewichtsverlust bei Patienten mit entzündlicher Komponente der Tumorerkrankung erlangen könnte und welches dazu die optimale Dosierung ist. Der postulierte Mechanismus könnte über eine Hemmung des Entzündungsprozesses laufen. Dieser Effekt könnte im optimalen Fall labormässig nachverfolgt werden.

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**keywords**
- Revlimid, cancer cachexia,
- -

**project homepage**
- -

**project partner**
- -

**type of project**
- clinical studies

**status**
- aborted

**start of project**
- 2009

**end of project**
- 2012

**additional information**

Primary Outcome Measures:
- Lean Body Mass [ Time Frame: after 8 weeks treatment ] [ Designated as safety issue: No ]
- and Handgrip Strength [ Time Frame: after 8 weeks treatment ] [ Designated as safety issue: No ]

Secondary Outcome Measures:
- SAEs [ Time Frame: for 12 weeks ] [ Designated as safety issue: Yes ]
•nutritional intake [ Time Frame: after 8 weeks of treatment ] [ Designated as safety issue: No ]

•physical functioning [ Time Frame: after 8 weeks of treatment ] [ Designated as safety issue: No ]

•inflammation [ Time Frame: for 8 weeks ] [ Designated as safety issue: No ]

•eating related symptoms (FAACT) [ Time Frame: after 8 weeks of treatment ] [ Designated as safety issue: No ]

•tumour dynamics (CT) [ Time Frame: after 8 weeks of treatment ] [ Designated as safety issue: No ]

Cancer cachexia syndrome (CCS) is frequent, causing high morbidity and mortality in affected ones. The mechanism is catabolism caused by the tumour. CRP is a surrogate marker for catabolism. There are no effective treatment options against CCS. Lenalidomide, a derivate of thalidomide, is an immunomodulatory drug (IMiD®). One of its' main effect is a decrease in inflammatory cytokines. As CCS treatment, thalidomide has shown in a randomized controlled trial to stabilize lean body mass. The effect of lenalidomide in solid tumour patients was negligible although, there might be a decrease in tumour progression. However, even if lenalidomide may be uninteresting as an anticancer treatment it might affect CCS dynamics. Respective data are currently lacking. Therefore, a dose level where an anticancer effect could be expected was chosen (group A). Relevant anti-inflammatory effect may occur below the commonly used doses to achieve tumour control, which is expected to be the main anti-cachexia effect. Therefore, a second CRP-response guided treatment arm (group B) was chosen.
Hypothesis: To test whether the response rate under new standard basic cachexia management will be at the estimated 5% and with lenalidomide (either fixed dose or CRP-guided dose) in addition to basic cachexia management at least 25%.

The primary objective of this study is to assess the efficacy of lenalidomide on lean body mass and handgrip strength in advanced solid tumour patients with inflammatory CCS.

Condition Intervention Phase
Cancer Cachexia Syndrome
Drug: Lenalidomide
Other: basic cachexia management (prokinetics, physical activity counselling, nutritional counselling)
Phase I
Phase II

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Arms Assigned Interventions
fix dose lenalidomide 25mg, basic cachexia management: Experimental
dose reduction according to toxicity possible
Intervention: Drug: Lenalidomide Drug: Lenalidomide
25mg od, dose reduction according to toxicity
Other Name: Revlimid
CRP-response guided lenalidomide, basic cachexia management: Experimental
start with 5mg od and increase of dosage to 10mg, 15mg or 25mg until CRP response (50% decrease)
Intervention: Drug: Lenalidomide Drug:
Lenalidomide
start with 5mg od and increase of dosage to 10mg, 15mg or 25mg until CRP response (50% decrease)
Other Name: Revlimid
placebo: Experimental
to generate data about basic cachexia management, no direct comparator for treatment arms efficacy
Intervention: Other: basic cachexia management (prokinetics, physical activity counselling, nutritional counselling) Other: basic cachexia management (prokinetics, physical activity counselling, nutritional counselling)
twice during study

Swissmedic notification number 2009DR2214
responsible person PD Dr. med. Florian Strasser