

Trial record 1 of 1 for: AIO-YMO-0111

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## Trial of S-1 Maintenance Therapy in Metastatic Esophagogastric Cancer (MATEO)

**This study is currently recruiting participants.** (see [Contacts and Locations](#))

Verified July 2015 by AIO-Studien-gGmbH

**Sponsor:**

AIO-Studien-gGmbH

**Collaborators:**

Taiho Pharmaceutical Co., Ltd.  
Nordic Pharma SAS

**Information provided by (Responsible Party):**

AIO-Studien-gGmbH

**ClinicalTrials.gov Identifier:**  
NCT02128243

First received: April 29, 2014

Last updated: July 10, 2015

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[History of Changes](#)

[Full Text View](#)

[Tabular View](#)

[No Study Results Posted](#)

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### Purpose

The aim is to assess the relative efficacy of S-1 de-escalation therapy vs. continuation of chemotherapy after induction therapy in patients with metastatic esophagogastric cancer in terms of overall survival.

| <u>Condition</u>                          | <u>Intervention</u>  | <u>Phase</u> |
|---|--|--------------|
| Metastatic Esophagogastric Adenocarcinoma | Drug: S-1 de-escalation<br>Drug: Chemotherapy by Investigator's choice | Phase 2      |

Study Type: Interventional

Study Design: Allocation: Randomized

Endpoint Classification: Safety/Efficacy Study

Intervention Model: Parallel Assignment

Masking: Open Label

Primary Purpose: Treatment

Official Title: Randomized Controlled Trial of S-1 Maintenance Therapy in Metastatic Esophagogastric Cancer

### Resource links provided by NLM:

[Drug Information](#) available for: [Fluorouracil](#) [Cisplatin](#) [Oxaliplatin](#)

[U.S. FDA Resources](#)

### Further study details as provided by AIO-Studien-gGmbH:

#### Primary Outcome Measures:

- Overall Survival (OS) [ Time Frame: approx. 12 month ] [ Designated as safety issue: No ]

OS will be defined as the time length between randomization and the date of death from any cause or the date of last follow-up in case of no documentation of death.

#### Secondary Outcome Measures:

- Progression-free survival (PFS) [ Time Frame: approx. 12 month ] [ Designated as safety issue: No ]

PFS will be defined as the time length between the date of randomization and the date of first disease progression or death (whichever occurs first).

- Quality of Life [ Time Frame: approx. 12 month ] [ Designated as safety issue: No ]

Quality of life will be evaluated using the validated European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ)-C30 questionnaire and the gastric module STO22.

**Other Outcome Measures:**

- Malnutrition [ Time Frame: approx. 12 month ] [ Designated as safety issue: No ]

Explorative descriptive statistical methods will be applied to describe the results of the Nutritional Risk Screening stratified by visit and treatment arm.

- Overall Survival of non-randomized patients [ Time Frame: approx. 12 month ] [ Designated as safety issue: No ]

For exploratory purposes, the overall survival experience of non-randomized patients will be considered. The survival time is defined as the time length between start of induction therapy and the date of death from any cause or the date of last follow-up in case of no documentation of death.

- Adverse Events [ Time Frame: approx. 12 month ] [ Designated as safety issue: Yes ]

For descriptive analysis of toxicity/safety, summary tables will be presented showing the total number of patients reporting at least one specific event stratified by System Organ Class, Common terminology criteria for adverse events (CTCAE) term, CTCAE grade and causality.

Estimated Enrollment: 400  
 Study Start Date: September 2014  
 Estimated Study Completion Date: September 2018  
 Estimated Primary Completion Date: September 2018 (Final data collection date for primary outcome measure)

| Arms   | Assigned Interventions  |
|--|---|
| <p>Experimental: Arm A: De-escalation therapy</p> <p>Patients in Arm A will continue with S-1 de-escalation phase starting at week 13 until disease progression, toxicities requiring discontinuation, withdrawal of consent, pregnancy, death or lost to follow up whichever occurs first. In patients with drug-related severe toxicity S-1 dose will be adjusted or study treatment will be terminated.</p> | <p>Drug: S-1 de-escalation</p> <p>S-1 30 mg/m<sup>2</sup> bid d1-14 q21d</p> <p>Other Name: Teysuno</p>   |
| <p>Experimental: Arm B: Chemotherapy by Investigator's choice</p> <p>Patients in Arm B will continue to receive the same polychemotherapy as during induction therapy until tumor progression, toxicities requiring discontinuation, withdrawal of consent, pregnancy, death or loss to follow up whichever occurs first.</p>  | <p>Drug: Chemotherapy by Investigator's choice</p> <p>Polychemotherapy administration as in induction therapy consists of a platinum and fluoropyrimidine compound as well as optional a taxane / an anthracycline compound.</p> <p>Two-Drug combinations:</p> <p>FLO / mod. FOLFOX-6 Cisplatin, S-1</p> <p>Three-drug combinations:</p> <p>EOX/EOF FLOT</p> <p>Other Names:</p> <ul style="list-style-type: none"> <li>FLO regimen</li> <li>- Oxaliplatin 85 mg/m<sup>2</sup></li> <li>- Leucovorin 200 mg/m<sup>2</sup></li> <li>- 5-Fluorouracil 2600 mg/m<sup>2</sup></li> <li>mod. FOLFOX-6 regimen</li> <li>- Leucovorin 400 mg/m<sup>2</sup></li> <li>- 5-Fluorouracil 400 mg/m<sup>2</sup></li> <li>- 5-Fluorouracil 2400 mg/m<sup>2</sup></li> <li>Cisplatin / S-1</li> <li>- Cisplatin 75 mg/m<sup>2</sup></li> </ul> |

- - S-1 25mg/m<sup>2</sup>
- EOX/EOF
- - Epirubicin 50 mg/m<sup>2</sup>
- - Oxaliplatin 130 mg/m<sup>2</sup>
- - Capecitabine 625 mg/m<sup>2</sup>
- FLOT
- - Docetaxel 50 mg/m<sup>2</sup>
- - Leucovorin 200 mg/m<sup>2</sup>

#### Detailed Description:

Open-label, multi-center, controlled, randomized, parallel-group phase II trial in patients with metastatic esophagogastric cancer having received induction chemotherapy.

Patients will be registered before the initiation of first-line chemotherapy regimen. This 12-week induction therapy will consist of one of the following regimens: FLO/mod. FOLFOX-6, Cisplatin/S-1, FLOT or EOX/EOF (see interventions for specification of regimens). Regarding dose adjustments, Investigators should refer to Section 6.3 and to the summary of product characteristics of the chemotherapeutic agents. Patients having finished the preplanned induction therapy without tumor progression (i.e. with complete remission (CR), partial remission (PR) or stable disease (SD) according to Response Evaluation Criteria in Solid Tumors (RECIST) Criteria Version 1.1) at week 12, being able to swallow capsules and having Eastern Cooperative Oncology Group (ECOG) performance score of 0-1 will be randomized in a 2:1 ratio to receive Arm A or B.

In Arm A patients will continue with S-1 de-escalation phase starting at week 13 until disease progression, toxicities requiring discontinuation, withdrawal of consent, pregnancy, death or lost to follow up whichever occurs first. In patients with drug-related severe toxicity S-1 dose will be adjusted or study treatment will be terminated.

In Arm B patients will continue to receive the same polychemotherapy as during induction therapy until tumor progression, toxicities requiring discontinuation, withdrawal of consent, pregnancy, death or loss to follow up whichever occurs first.

#### Eligibility

Ages Eligible for Study: 18 Years and older  
 Genders Eligible for Study: Both  
 Accepts Healthy Volunteers: No

#### Criteria

##### Inclusion Criteria:

1. Signed written informed consent incl. participation in translational research
2. Male or female patient 18 years or older
3. Histologically confirmed metastatic or locally advanced unresectable gastric adenocarcinoma or adenocarcinoma of the esophagus or the esophagogastric junction (Her-2/neu negative or with unknown Her-2/neu status)
4. Measurable disease as per RECIST 1.1 criteria
5. Adjuvant/neoadjuvant or perioperative chemotherapy or (chemo-)radiotherapy must have been finished at least 6 months before study entry
6. No previous systemic treatment (i.e. chemotherapy) for metastatic disease
7. ECOG Performance Score 0-1 (Karnofsky Performance status  $\geq$  80%)
8. Ability for oral intake of the study drug, patients with tumor-related problems with oral intake might be registered if the symptom is expected to be improved during induction therapy (e.g. due to a tumor stenosis)
9. Female patient of childbearing potential (i.e. did not undergo surgical sterilization - hysterectomy, bilateral tubal ligation, or bilateral oophorectomy - and is not post-menopausal for at least 24 consecutive months) with a negative pregnancy test
10. Hematology and biochemistry laboratory results within the limits normally expected for the patient population, defined by the following:
  - Absolute neutrophil count  $\geq$  1500/ $\mu$ l
  - Platelet count  $\geq$  100000/ $\mu$ l
  - Leukocyte count  $>$  3000/ $\mu$ l
  - Hemoglobin  $\geq$  9 g/dL or 5.59 mmol/l, previous transfusions ( $>$ 3 days) of erythrocytes are allowed
  - Total bilirubin  $\leq$  1.5 times the upper limit of normal (ULN), in patients with known Meulengracht syndrome  $\leq$  3x ULN
  - Aspartate aminotransferase (AST)  $\leq$  3x ULN in absence of liver metastases, or  $\leq$  5x ULN in presence of liver metastases
  - Alanine aminotransferase (ALT)  $\leq$  3x ULN in absence of liver metastases, or  $\leq$  5x ULN in presence of liver metastases
  - Creatinine clearance  $\geq$ 30 mL/min according to Cockcroft-Gault formula

##### Exclusion Criteria:

1. Previous major surgery within the last 28 days before the start of the induction treatment. The implantation of a central venous access (e.g. port-a cath system) is allowed.
2. History of other malignant tumors within the last 5 years, except basal cell carcinoma or curatively excised cervical carcinoma in situ
3. Known brain metastases
4. Concurrent radiotherapy involving target lesions used for this study. Concurrent palliative radiation for non-target lesions is allowed if other target lesions are available outside the involved field; previous radiotherapy including target lesions must have been finished at least 28 days before start of induction treatment.
5. Previous systemic treatment (i.e. chemotherapy) for metastatic disease
6. Known active Hepatitis B virus (HBV), Hepatitis C virus (HCV) infection or documented HIV infection
7. Serious concomitant disease or medical condition that by judgment of the Investigator renders the patient at high risk of treatment complications
8. Clinically relevant coronary artery disease (NYHA functional angina classification III/IV), congestive heart failure (NYHA III/IV), clinically relevant cardiomyopathy, history of myocardial infarction in the last 3 months, or high risk of uncontrolled arrhythmia
9. Female patient pregnant or breast feeding
10. Female patient of childbearing potential (i.e. did not undergo surgical sterilization - hysterectomy, bilateral tubal ligation, or bilateral oophorectomy - and is not post-menopausal for at least 24 consecutive months) not willing to use an adequate method of contraception to avoid pregnancy throughout the study and for up to 26 weeks after the end of treatment. Male patient not willing to use an adequate method of contraception to avoid conception throughout the study and for up to 26 weeks after the end of treatment in such a manner that the risk of pregnancy is minimized.
11. Concurrent treatment with other experimental drugs or participation in another clinical trial with any investigational drug within 60 days prior to start of induction
12. Chronic diarrhea or short bowel syndrome
13. Known hypersensitivity to S-1, other fluoropyrimidines or platinum compounds. Contraindication to receive S-1 as per current Summary of Product Characteristics. Known Dihydropyrimidine dehydrogenase (DPD) deficiency
14. Grade  $\geq 2$  peripheral neuropathy
15. Known drug abuse/alcohol abuse

## **Contacts and Locations**

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see [Learn About Clinical Studies](#).

Please refer to this study by its ClinicalTrials.gov identifier: NCT02128243

### **Contacts**

Contact: Helge Schröder, Dipl.- Biol. +49 - 30 - 8145 344 ext 35 [helge.schroeder@aio-studien-ggmbh.de](mailto:helge.schroeder@aio-studien-ggmbh.de)

### **Locations**

#### **Germany**

NCT-Med. Onkologie

Heidelberg, Baden-Württemberg, Germany, 69120

Contact: Georg Martin Haag, Dr. +49-6221 ext 5637630 [GeorgMartin.Haag@med.uni-heidelberg.de](mailto:GeorgMartin.Haag@med.uni-heidelberg.de)

**Recruiting**

### **Sponsors and Collaborators**

AIO-Studien-gGmbH

Taiho Pharmaceutical Co., Ltd.

Nordic Pharma SAS

### **Investigators**

Principal Investigator: Georg Martin Haag, Dr. NCT-Med. Onkologie

## **More Information**

Additional Information:

[Working Group for Medical Oncology \(AIO\) from the German Cancer Society \(DKG\)](#) 

No publications provided

Responsible Party: AIO-Studien-gGmbH  
ClinicalTrials.gov Identifier: [NCT02128243](#) [History of Changes](#)  
Other Study ID Numbers: **AIO-YMO-0111**, 2013-002742-37  
Study First Received: April 29, 2014  
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Health Authority: Germany: Federal Institute for Drugs and Medical Devices  
Sweden: Medical Products Agency  
Austria: Agency for Health and Food Safety

Additional relevant MeSH terms:

|                                     |  |
|-------------------------------------|--|
| Adenocarcinoma                      | Antimetabolites, Antineoplastic                |
| Carcinoma                           | Antineoplastic Agents                          |
| Neoplasms                           | Immunologic Factors                            |
| Neoplasms by Histologic Type        | Immunosuppressive Agents                       |
| Neoplasms, Glandular and Epithelial | Molecular Mechanisms of Pharmacological Action |
| Cisplatin                           | Pharmacologic Actions                          |
| Fluorouracil                        | Physiological Effects of Drugs                 |
| Oxaliplatin                         | Radiation-Sensitizing Agents                   |
| Antimetabolites                     | Therapeutic Uses                               |

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