KURZPROTOKOLL
Tallisur

Öffentlicher Titel	Phase IV Studie zu Trifluridine/Tipiracil beim metastasiertem Kolorektalkarzinom
Wissenschaftl. Titel	Prospective, multicenter, open-label phase IV trial of trifluridine/tipiracil to evaluate the health-related quality of life in patients with metastatic colorectal cancer
Kurztitel	Tallisur
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, zweiarmig
Studienphase	Phase IV
Erkrankung	Verdauung: Darmkrebs (Kolorektales Karzinom): Zweitlinie oder höher
Einschlusskriterien	- Patients had provided written informed consent prior to any procedure - Patients of >= 18 years of age at the time of signing the informed consent - Histologically or cytologically confirmed UICC stage IV carcinoma of colon or rectum with metastasis (metastatic colorectal cancer) with need for treatment due to progression - At least one measurable or non-measurable lesion as defined by RECIST version 1.1 32 - Patients who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents - Patients able to take medications orally (ie, no feeding tube) - mCRC patients independent from their ECOG performance status at study enrolment - Adequate organ function as defined by the following laboratory values obtained within 7 days prior to first administration of FTD/TPI on Day 1 of Cycle 1 (haematology and laboratory values for patients who are administered only BSC need not be obtained within 7 days prior to observation Cycle 1) - a. Absolute neutrophil count of >= 1.5 × 10^9/L - b. Platelet count >= 75 × 10^9/L - c. Total serum bilirubin of <= 1.5 upper limit of normal (ULN) - d. Aspartate aminotransferase (AST/SGOT) and alanine aminotransferase (ALT/SGPT) <= 3.0 × ULN; if liver function abnormalities are due to underlying liver metastasis, AST and ALT <= 5 × ULN - e. Calculated creatinine clearance (CrCl) >= 30 mL/min - Only applicable for females who receive treatment with FTD/TPI (Group A): - Females of childbearing potential (FCBPs) must have a negative pregnancy test (urine or serum) within 7 days prior to enrolment. FCBPs must agree to use highly effective contraceptive measures with a failure rate of less than 1% per year when used consistently and correctly as defined in Section 4.1 of the CTFG guidance “Recommendations related to contraception and pregnancy testing in clinical trials” during the entire study treatment with FTD/TPI and up to 6 months after the discontinuation of study drug FTD/TPI. Complete sexual abstinence is acceptable as a highly effective contraceptive method only if the subject is refraining from heterosexual intercourse during the entire study treatment with FTD/TPI and up to 6 months after the discontinuation of study drug FTD/TPI and the reliability of sexual abstinence is in line with the preferred and usual lifestyle of the subject. Women using hormonal contraceptives should agree to add a barrier contraceptive method. A woman will be considered as being of childbearing potential unless she has gone through menopause for at least 1 year (i.e. minimum of one year without menses) or unless she has a history of tubal ligation, bilateral oophorectomy or hysterectomy that is clearly documented in the patient’s source documents.

- Only applicable for males who receive treatment with FTD/TPI (Group A): Males must agree to use effective contraceptive measures or to practice complete abstinence during the study treatment with FTD/TPI and up to 6 months after the discontinuation of study drug FTD/TPI
- Patients capable to understand the purposes and risks of the study, who are willing and able to participate in the study, who are able to understand and to fill in the questionnaire and from whom written and dated informed consent to participate in the study has been obtained

Ausschlusskriterien

- Patients requesting not to be treated with FTD/TPI but considering other tumour treatment (e.g. palliative radiotherapy)
- Concurrently active malignancies other than mCRC excluding malignancies that are disease free for more than 5 years, adequately treated basal cell or squamous cell skin cancer or carcinoma-in-situ deemed cured by adequate treatment, e.g. in situ cervical, breast or prostate cancer.
- Brain or leptomeningeal metastases not controlled through surgery or radiotherapy
- Active infection (i.e, body temperature >=38°C due to infection)
- Intestinal obstruction
- Uncontrolled diarrhea
- Uncontrolled diabetes
- Pulmonary fibrosis or interstitial pneumonitis
- Renal failure with CrCl <30 ml/min
- Hepatic failure >= CTCAE version 4 Grade 3
- Cerebrovascular accident within the last 6 months
- Myocardial infarction within the last 6 months, severe/unstable angina, symptomatic congestive heart failure New York Heart Association (NYHA) class III or IV
- Gastrointestinal hemorrhage within last 3 months
- Autoimmune disorders or history of organ transplantation that require immunosuppressive therapy.
- Psychiatric disease that may increase the risk associated with study participation or study drug administration, or may interfere with the generation of QoL results
- Any other severe concomitant disease or disorder, including the presence of laboratory abnormalities, which places the subject at unacceptable risk or which could influence patient’s ability to participate in the study and his/her safety during the study or interfere with interpretation of study results
- Treatment with any of the following within the specified time frame prior to first administration of FTD/TPI or Day 1 of observation cycle 1 (if no administration of FTD/TPI):
- a. Major surgery within prior 4 weeks (the surgical incision should be fully healed prior to study drug administration)
- b. Any anticancer therapy within prior 2 weeks
- c. Extended field radiation within prior 4 weeks or limited field radiation within prior 2 weeks
- Participation in any other clinical trial or treatment with any experimental drug or other experimental therapy within 28 days prior to first administration of FTD/TPI or Day 1 of observation cycle 1 (if no administration of FTD/TPI); participation in a non-interventional study is permitted
- Patients who have already received FTD/TPI

	- Unresolved non-haematological toxicity of >= CTCAE version 4 Grade III attributed to prior therapies excluding anemia, alopecia, skin pigmentation and platinum induced neurotoxicity - Hypersensitivity to trifluridine, tipiracil or any of the excipients - Hereditary galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption - Pregnant or breast-feeding female - Inappropriate for entry into this study in the judgment of the investigator - Patient has been committed to an institution by virtue of an order issued either by the judicial or the administrative authorities. - Patients possibly dependent from the investigator including the spouse, children and close relatives of any investigator
Alter	18 Jahre und älter
Prüfzentren	**Universitätsklinikum Gießen und Marburg, Standort Marburg** (Geschlossen) Hämatologie, Onkologie und Immunologie Baldingerstraße 35043 Marburg Michaela Weintraut Tel: 06421 5863942 Fax: 06421 5862703 studien-onkologie@uni-marburg.de
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