KURZPROTOKOLL
Elderly_AIO KRK 0117

Öffentlicher Titel	Phase II Studie zu Aflibercept + 5-FU vs. FOLFOX als Erstlinientherapie bei älteren Patienten mit metastasiertem Kolorektalkarzinom
Wissenschaftl. Titel	Aflibercept and 5-FU vs. FOLFOX as 1st line treatment for elderly or frail elderly patients with metastatic colorectal cancer
Kurztitel	Elderly_AIO KRK 0117
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase II
Erkrankung	Verdauung: Darmkrebs (Kolorektales Karzinom): Erstlinie

Einschlusskriterien

- To enter this trial the oncologist has to confirm, that the patient was in his or her opinion not a candidate for standard full-dose combination therapy. Moreover, the oncologist has to state the reason for entering the trial (Advanced age alone versus both age and frailty). As an operational definition for frailty the G8 screening tool will be used upon inclusion of the patient in a standardized manner. Briefly, G8 is an established screening tool that includes seven items from the Mini Nutritional Assessment (MNA) and an age-related item (<80, 80 to 85, or 85 years). The total score can range from 0 to 17. The result on the G8 is considered abnormal if the score is <=14, indicating a geriatric risk profile.
- Patients have to have histologically confirmed mCRC with unidimensionally measurable inoperable advanced or metastatic disease
- ECOG performance status of 2 or better.
- Life expectancy of 3 months or longer at enrolment
- Patients >70 years with no upper age limit
- Previous adjuvant chemotherapy is allowed if completed more than 6 months before randomisation
- Previous rectal (chemo)radiotherapy is allowed if completed more than 6 months before randomisation
- Hematological status:
- -> Neutrophils (ANC) >= 1.5 x 10^9/L
- -> Platelets >= 100 x 10^9/L
- -> Hemoglobin >= 9 g/dL
- Adequate renal function:
- -> Serum creatinine level <= 1.5 x upper limit normal (ULN)
- Adequate liver function:
- -> Serum bilirubin <= 1.5 x upper limit normal (ULN)
- -> Alkaline phosphatase <= 2.5 x ULN (unless liver metastases are present, then < 5 x ULN in that case)
- -> AST and ALT < 3 x ULN (unless liver metastases are present then < 5 x ULN in that case)
- Proteinuria < 2+ (dipstick urinalysis) or <= 1 g/24 hour
- Signed and dated informed consent, and willing and able to comply with protocol requirements
- Regular follow-up feasible
- Male patients with a partner of childbearing potential must agree to use effective contraception (Pearl Index < 1) during the course of the trial and at least 3 months after last administration of the study drug.

Ausschlusskriterien

- Prior systemic chemotherapy for mCRC
- Other concomitant or previous malignancy, except:

- -> Adequately treated in-situ carcinoma of the uterine cervix
- -> Basal or squamous cell carcinoma of the skin
- -> Cancer in complete remission for > 5 years
- Any other serious and uncontrolled non-malignant disease, major surgery or traumatic injury within the last 28 Days
- History or evidence upon physical examination of CNS metastasis unless adequately treated (irradiation and no seizure with appropriate treatment)
- Uncontrolled hypercalcemia
- Pre-existing peripheral neuropathy (NCI grade >=2)
- Concomitant protocol unplanned antitumor therapy (e.g. chemotherapy, molecular targeted therapy, immunotherapy),
- Treatment with any other investigational medicinal product within 28 days prior to study entry.
- Significant cardiovascular disease:
- -> Cardiovascular accident or myocardial infarction or unstable angina 6 months before start of study treatment
- -> Severe cardiac arrhythmia
- -> New York Heart Association grade >=2 congestive heart failure
- ->Uncontrolled hypertension (defined as systolic blood pressure >150 mmHg and/or diastolic blood pressure >100 mmHg), or history of hypertensive crisis, or hypertensive encephalopathy.
- -> History of stroke or transient ischemic attack <=6 months before start of study treatment
- -> Coronary/peripheral artery bypass graft <=6 months before start of study treatment.
- -> Deep vein thrombosis or thromboembolic events <=1 month before start of study treatment
- Patients with known allergy to any excipient to study drugs,
- Any of the following within 3 months prior to randomization: Grade 3-4 gastrointestinal bleeding/hemorrhage, treatment resistant peptic ulcer disease, erosive oesophagitis or gastritis, infectious or inflammatory bowel disease, diverticulitis, pulmonary embolism or other uncontrolled thromboembolic event.
- Bowel obstruction.
- Treatment with CYP3A4 inducers unless discontinued > 7 days prior to randomization
- Known dihydropyrimidine dehydrogenase (DPD) deficiency
- Involvement in the planning and/or conduct of the study (applies to both Sanofi staff and/or staff of sponsor and study site)
- Patient who might be dependent on the sponsor, site or the investigator
- Patient who has been incarcerated or involuntarily institutionalized by court order or by the authorities § 40 Abs. 1 S. 3 Nr. 4 AMG.
- Patients who are unable to consent because they do not understand the nature, significance and implications of the clinical trial and therefore cannot form a rational intention in the light of the facts [§ 40 Abs. 1 S. 3 Nr. 3a AMG].

Alter >= 70 Jahre

Status Aktiv

KURZPROTOKOLL
Elderly_AIO KRK 0117

Prüfzentren	**Krankenhaus Nordwest GmbH** Institut für klinisch-onkologische Forschung Steinbacher Hohl 2-26 60488 Frankfurt am Main Petra Zimmermann Tel: 069 7601 4552 Fax: 069 7601 3655 zimmermann.petra@khnw.de
Sponsor	IKF GmbH
Förderer	Sanofi Aventis GmbH
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03530267 (primäres Register) EudraCT 2017-000329-11