KURZPROTOKOLL
PROCAPP

Öffentlicher Titel	Phase III Studie zu Mapsial® vs Urea Handcreme als Prophylaxe gegen "hand-foot" Syndrom (HFS) bei gastrointestinalen Tumoren oder Brustkrebs
Wissenschaftl. Titel	A Randomized, Open-label Phase III Trial of Mapisal® Versus an Urea Hand-foot Cream as Prophylaxis for Capecitabine-induced Hand-foot Syndrome in Patients With Gastrointestinal Tumors or Breast Cancer
Kurztitel	PROCAPP
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase III
Erkrankung	Verdauung: Bauchspeicheldrüsenkrebs (Pankreaskarzinom): weitere Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): weitere Verdauung: Gastrointestinale Stromatumoren (GIST): weitere Geschlechtsorgane: Brustkrebs: sonstige Studien für Brustkrebs Verdauung: Darmkrebs (Kolorektales Karzinom): weitere Verdauung: Leberkrebs (Hepatozelluläres Karzinom): weitere
Ziele	- To assess the efficacy of Mapisal to prevent hand-foot syndrome (HFS) of any grade in patients treated with capecitabine based on a standardised patient diary - To compare efficacy and safety with respect to: 1. HFS by grade over time 2. Time to development of HFS > grade 1 3. Time to change of HFS treatment strategy 4. Time to capecitabine dose reduction or dose interruption 5. Evaluation of capecitabine dose intensity 6. QoL analyses (EORTC QLQ C30 and DLQI)
Einschlusskriterien	- Signed written informed consent - Male or female >=18 years of age - Patients with gastrointestinal tumors or breast cancer who will be treated with capecitabine according to label - Palliative or adjuvant chemotherapy with capecitabine - Life expectancy of least 12 weeks - WHO performance status 0-2 - Adequate contraception - Willingness to fill in QoL forms - Laboratory requirements: 1. Platelet count >=100 × 109/L 2. Leukocyte count > 3.0 × 109/L 3. Hemoglobin >= 10.0 g/dL
Ausschlusskriterien	- Previous chemotherapy with capecitabine or liposomal doxorubicine, or any other substance, i.e. tyrosine kinase inhibitors (such as sorafenib and sunitinib) that may induce HFS - Radiotherapy or surgery within 4 weeks before start of treatment - Resolution of all chemotherapy- or radiotherapy-related toxicities to grade 1 or lower except for stable sensory neuropathy < grade 2 and alopecia, excluding dermatological toxicities - Dermatologic diseases that could interfere with the result of the clinical trial - Known drug/ alcohol abuse - Pregnant or breast feeding patients - Participation in another clinical trial and patient received investigational drug within the last 30 days prior to treatment start (i.e. follow-up within a preceding trial is not exclusionary) - Known allergic reactions to any of the ingredients of the ointments or capecitabine
Alter	18 Jahre und älter

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Fallzahl	10
Sponsor	AIO-Studien GmbH
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Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01626781