KURZPROTOKOLL
SAKK 96/12

Öffentlicher Titel	Verhinderung von symptomatischen Komplikationen am Skelett mit Denosumab verabreicht alle 4 Wochen gegenüber alle 12 Wochen
Wissenschaftl. Titel	Prevention of Symptomatic Skeletal Events with Denosumab Administered every 4 Weeks versus every 12 Weeks – A Non-Inferiority Phase III Trial
Kurztitel	SAKK 96/12
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Krebserkrankungen der männlichen Geschlechtsorgane: Prostatakrebs - sonstige Studien Geschlechtsorgane: Brustkrebs: sonstige Studien für Brustkrebs
Einschlusskriterien	- Signed informed consent - ECOG Performance 0-2 - Age >= 18 years - Confirmed diagnosis of breast or prostate cancer before randomization - Patient has metastatic breast cancer (stage IV, all subtypes allowed except small cells) or prostate cancer (stage IV, exception: small cells) and bone metastases and is planned to receive or is receiving antineoplastic treatment - Patients with prostate cancer must have evidence of disease Progression on continuous androgen deprivation therapy (CRPC) - Patients must have >= three bone metastases (lytic or blastic or mixed) - Corrected serum calcium >= 2 mmol/l and <= 3 mmol/l (medical treatments to obtain serum calcium levels in the normal range are allowed, as far as no denosumab is used. Maximally one dose of bisphosphonates in the case of hypercalcemia is allowed, if the bisphosphonate was applied at least three weeks before the first dose of denosumab) - Liver transaminases not more than 1.5 x ULN or not more that 3 x ULN with liver metastases. Serum total bilirubin <= 1.5 x ULN (<= 2.0 x ULN in case of known Gilbert's disease)
Ausschlusskriterien	- Definite contraindication for denosumab (e.g. hypocalcemia [Albumin-corrected serum calcium < 2.0 mmol/l]) - History or current evidence of osteonecrosis of the jaw (ONJ) - Non-healed mucosa in oral cavity (by surgery or as a side effect of any other Treatment) - Jaw or dental conditions that require oral surgery or if surgery or invasive dental procedures are planned - Prior use of denosumab for bone metastases or bisphosphonates to treat bone metastases. Patients treated with denosumab or bisphosphonates against osteopenia or osteoporosis are followed to enter the trial if the last dose was more than 28 days before randomization - Patients with known osteoporosis (T-score <= -2.5) at study entry - Radiotherapy or surgery to the bone within the last two weeks before randomization or planned within six weeks after randomization - Presence or history of CNS metastases or leptomeningeal disease. A MRI Evaluation within twelve weeks before randomization must be performed in case of suspicious symptoms
Alter	18 Jahre und älter

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Sponsor	Sakk Swiss Group
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02051218 (primäres Register) EudraCT 2014-001189-87