KURZPROTOKOLL
ARAMIS

Öffentlicher Titel	Phase-III-Studie zur Wirksamkeit und Sicherheit von ODM-201 bei männlichen Hochrisikopatienten mit nicht metastasiertem, kastrationresistentem Prostatakrebs
Wissenschaftl. Titel	Multizentrische, randomisierte, doppelblinde, placebokontrollierte Phase-III-Studie zur Wirksamkeit und Sicherheit von ODM-201 bei männlichen Hochrisikopatienten mit nicht metastasiertem, kastrationresistentem Prostatakrebs
Kurztitel	ARAMIS
Studienart	multizentrisch, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Krebserkrankungen der männlichen Geschlechtsorgane: Prostatakrebs - Erstlinie
Einschlusskriterien	- Castration-resistant prostate cancer (CRPC) with castrate level of serum testosterone. - Prostate-specific antigen doubling time of 10 months and PSA > 2ng/ml. - Eastern Cooperative Oncology Group (ECOG) performance status of 0-1. - Blood counts at screening: haemoglobin 9.0 g/dl,absolute neutrophil count 1500/µl, platelet count 100,000/µl. - Screening values of serum alanine aminotransferase (ALT) and/or aspartate transaminase (AST) 2.5 x upper limit of normal (ULN), total bilirubin 1.5 x ULN, creatinine 2.0 x ULN. - Sexually active patients, unless surgically sterile, must agree to use condoms as an effective barrier method and refrain from sperm donation during the study treatment and for 3 months after the end of the study treatment.
Ausschlusskriterien	- History of metastatic disease or presence of detectable metastases. - Acute toxicities of prior treatments and procedures not resolved to grade 1 or baseline before randomisation. - Prior treatment with: second generation androgen receptor (AR) inhibitors, other investigational AR inhibitors, or CYP17 enzyme inhibitor. - Use of estrogens, 5- reductase inhibitors or AR inhibitors. - Prior chemotherapy or immunotherapy for prostate cancer. - Use of systemic corticosteroid. - Radiation therapy within 12 weeks before randomisation. - Severe or uncontrolled concurrent disease, infection or co-morbidity. - Treatment with bisphosphonate or denosumab within 12 weeks before randomisation. - Known hypersensitivity to the study treatment or any of its ingredients. - Major surgery within 28 days before randomisation. - Any of the following within 6 months before randomisation: stroke, myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft; congestive heart failure New York Heart Association (NYHA) Class III or IV. - Uncontrolled hypertension. - Prior malignancy. - Gastrointestinal disorder or procedure which expects to interfere significantly with absorption of study treatment. - Active viral hepatitis, active human immunodeficiency virus (HIV) or chronic liver disease. - Any condition that in the opinion of the investigator would impair the patients' ability to comply with the study procedures.
Alter	18 Jahre und älter

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Fallzahl	1500
Prüfzentren	**Universitätsklinikum Frankfurt** (Rekrutierung beendet) Zentrum für Chirurgie, Klinik für Urologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Dr. med. Severine Banek Tel: 069 6301-80072 Fax: 069 6301-84029 severine.banek@unimedizin-ffm.de
Sponsor	Bayer Healthcare
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02200614 EudraCT 2013-003820-36