

KURZPROTOKOLL ATLAS

Öffentlicher Titel	Phase III Studie zu Apalutamid bei fortgeschrittenem Hochrisiko-Prostatakrebs
Wissenschaftl. Titel	A Randomized, Double-blind, Placebo-controlled Phase 3 Study of JNJ-56021927 in Subjects with High-risk, Localized or Locally Advanced Prostate Cancer Receiving Treatment with Primary Radiation Therapy
Kurztitel	ATLAS
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Krebserkrankungen der männlichen Geschlechtsorgane: Prostatakrebs - Erstlinie
Einschlusskriterien	- Age $\geq$ 18 years - Indicated and planned to receive primary radiation therapy for prostate cancer - Histologically confirmed adenocarcinoma of an intact prostate, and 1 of the following at diagnosis: 1) Gleason score $\geq$8 and $\geq$cT2c, 2) Gleason score $\geq$7, PSA $\geq$20 nanogram per milliliters (ng/mL), and $\geq$cT2c - Charlson index (CCI) $\leq$3 - An Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) grade of 0 or 1 - Adequate organ function: (1) aspartate aminotransferase (AST), alanine aminotransferase (ALT), within normal limits (WNL), (2) serum creatinine less than ($<$) 1.5 milligram/deciliter (mg/dL) ($<$133 micromoles/Liter [mcmol/L]), (3) platelets greater than or equal to ($\geq$)140,000/microLiter (mcL), independent of transfusion and/or growth factors within 3 months prior to randomization, (4) Hemoglobin $\geq$ 12.0 gram/deciliter (g/dL) (7.4 millimoles [mmol], independent of transfusion and/or growth factors within 3 months prior to randomization - Participants who are sexually active (even men with vasectomies) and willing to use a condom and agree not to donate sperm during the trial - Signed, written, informed consent - Be able to swallow whole study drug tablets
Ausschlusskriterien	- Presence of distant metastasis, (clinical stage M1). Isolated pelvic nodal disease below the iliac bifurcation (clinical stage N1) is not an exclusion. Diagnosis of distant metastasis (clinical M stage; M0 versus M1a, M1b, M1c) and pelvic nodal disease (clinical N stage; N1 versus N0) will be assessed by central radiological review. Patients are considered eligible only if the central radiological review confirms clinical stage M0. - Prior treatment with gonadotropin releasing hormone (GnRH) analogue or anti-androgen or both for $>$3 months prior to randomization - Bilateral orchiectomy - History of pelvic radiation - Prior systemic (example [e.g.], chemotherapy) or local (e.g. radical prostatectomy, cryotherapy) treatment for prostate cancer - History of seizure or any condition that may predispose to seizure (including, but not limited to prior stroke, transient ischemic attack or loss of consciousness $\leq$ 1 year prior to randomization; brain arteriovenous malformation; or intracranial masses such as schwannomas and meningiomas that are causing edema or mass effect) - Prior treatment with enzalutamide, abiraterone acetate, orteronel, galeterone, ketoconazole, aminoglutethimide, estrogens, megestrol acetate, and progestational agents (including cyproterone acetate) for prostate cancer - Prior treatment with radiopharmaceutical agents (e.g., strontium-89) or immunotherapy (e.g., sipuleucel-T) for prostate cancer

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- Prior treatment with systemic glucocorticoids $\leq$ 4 weeks prior to randomization or is expected to require long-term use of corticosteroids during the study
- Use of 5-alpha reductase inhibitors (e.g., dutasteride, finasteride) $\leq$ 4 weeks prior to randomization
- Use of any investigational agent $\leq$ 4 weeks prior to randomization
- Current chronic use of opioid analgesics for $\geq$ 3 weeks for oral or $>$ 7 days for non-oral formulations
- Major surgery $\leq$ 4 weeks prior to randomization
- Current or prior treatment with anti-epileptic medications for the treatment of seizures
- Gastrointestinal conditions affecting absorption
- Known or suspected contraindications or hypersensitivity to apalutamide, bicalutamide or GnRH agonists or any of the components of the formulations
- Any condition for which, in the opinion of the investigator, participation would not be in the best interest of the subject

Alter

18 Jahre und älter

Prüfzentren

Universitätsmedizin 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

Janssen Research & Development

Registrierung in anderen Studienregistern

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