AFT 19 - A Phase 3 Study of Androgen Annihilation in High-Risk Biochemically Relapsed Prostate Cancer

ALLIANCE FOUNDATION TRIALS, LLC

Rahul Aggarwal, MD, University of California, San Francisco; Scott Eggener, MD, University of Chicago
Susan Halabi, PhD, Duke University; J. Kellogg Parsons, MD, MHS, University of California, San Diego
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TAP TO RETURN TO KIOSK MENU

rationale/ objective

study schema

key eligibility criteria

follow up

Randomized, open-label, three-arm, phase 3 study in men with biochemically recurrent prostate cancer and PSA doubling time ≤ 9 months at the time of study entry. Patients will be stratified by PSA doubling time (< 3 months vs. 3-9 months) and randomized in 1:1:1 fashion to one of three treatment arms:

1. Control arm consisting of degarelix monotherapy,
2. Experimental arm consisting of apalutamide in combination with degarelix, and
3. Experimental arm consisting of apalutamide, abiraterone acetate + prednisone, and degarelix.

Patients will be treated for a maximum duration of 52 weeks and then enter follow up phase until the time of PSA progression. Patients with PSA progression will be followed long term for development of castration resistance, first metastasis, and death.

RATIONALE

Primary

- To compare PSA progression-free survival in each of the experimental arms versus the control arm of degarelix monotherapy.

Secondary

- To compare PSA progression-free survival in testosterone-evaluable population in each experimental arm versus the control arm. Testosterone-evaluable population includes all patients who achieve serum testosterone recovery to > 50 ng/dL with subsequent PSA measurements sufficient for evaluation.
- To compare the 36-month PSA progression-free survival rate in each experimental arm versus the control arm.
- To compare the time to recovery of serum testosterone to greater than 50 ng/dL in each experimental arm versus the control arm.
- To compare the time to castration resistance in each experimental arm versus the control arm.
- To compare the metastasis-free survival in each experimental arm versus the control arm.
- To compare the overall survival in each experimental arm versus the control arm.
- To characterize the safety profile in each treatment arm.
- To compare short-term and long-term health-related quality of life (HRQOL) in each experimental arm versus the control arm.
- To compare the quality-adjusted PSA progression- survival (PSA progression-free survival multiplied by utility score) of patients in each experimental arm versus the control arm.

OBJECTIVE

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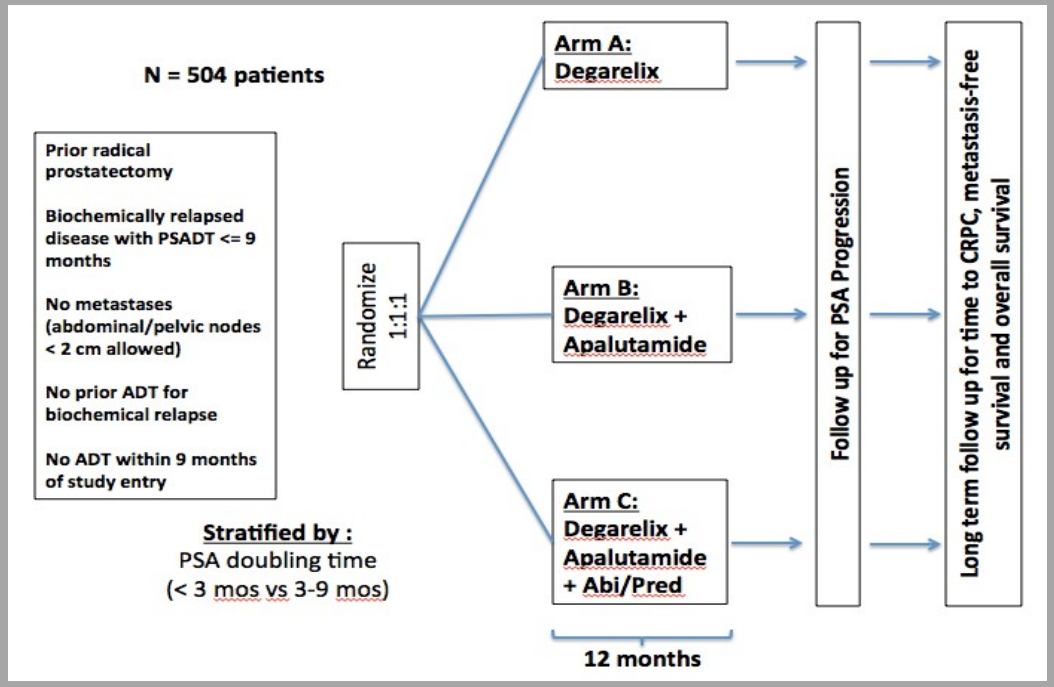

STUDY SCHEMA

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- Histologically confirmed prostate adenocarcinoma
- Prior radical prostatectomy
- Biochemically recurrent prostate cancer with PSA doubling time ≤ 9 months at the time of study entry
- Prior adjuvant or salvage radiation or not a candidate for radiation based upon clinical assessment of disease characteristics and patient co-morbidities
- Screening PSA > 0.5 ng/mL
- No definitive evidence of metastases on screening CT or MRI of abdomen/ pelvis and radionuclide whole body bone scan per the judgment of the investigator.
- Abdominal and/or pelvic lymph nodes measuring 2 cm or less in short axis diameter are allowed.
- Lesions identified on other imaging modalities (e.g. PSMA or choline PET) that are not visualized on CT and/or MRI or radionuclide bone scan are allowed.
- Equivocal lesions on bone scan should be followed up with additional imaging as clinically indicated.
- Screening serum testosterone > 150 ng/dL

KEY ELIGIBILITY CRITERIA

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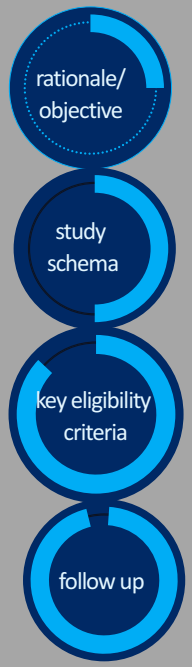

This trial (AFT-19) is funded by Janssen Pharmaceuticals.

Study Number: **AFT 19**
Study Phase: **Interventional Phase III**
Clinical Indication: **Biochemically recurrent prostate cancer after prior radical prostatectomy**
ClinicalTials.gov Identifier: **NCT03009981**
Number of Trial Patients: **504**
Estimated Trial Duration: **6 years**

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FUNDING SUPPORT | **STUDY DETAILS / CONTACT US**