### Title

LBA19 THE MEN'S EATING AND LIVING (MEAL) STUDY (CALGB 70807 [ALLIANCE]): A RANDOMIZED CLINICAL TRIAL OF A DIET INTERVENTION IN MEN ON ACTIVE SURVEILLANCE FOR PROSTATE CANCER




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INTRODUCTION AND OBJECTIVES: Indolent forms of PC or low-risk prostate cancer (LRPC) represent 50% of newly diagnosed PC. Definition of LRPC and AS candidates remains problematic due to the lack of relevant markers of PC aggressiveness and difficulties in assessing disease progression under AS. Current knowledge suggests that PC aggressiveness could be assessed by response to early ADT. Long-term administration of a 5-alpha-reductase inhibitor may prevent the development of PC and reverse LRPC. Preliminary results of a pilot series at 2 French urology centers in LRPC pts receiving 2 drugs (analogs and 5-alpha-reductase inhibitor) for 3 months (mo), show tumor regression in about 60% of cases and suggest that LRPC can be reversed by ADT. Our study aims at confirming these results on a larger scale.

METHODS: This was an open randomized phase III study comparing 2 treatment strategies. Arm A = AS after a single subcutaneous injection of Leuprorelin LP 11.25mg. Arm B = usual AS. Pts were eligible if they had a T1c or T2a PC, PSA inferior or equal to 10 ng/ml, Gleason score (GS) inferior or equal to 6 & staging Bx with 12 or more cores revealing the presence of positive cores & absence of core with tumor length $>$ 3mm. The main endpoint was negative Bx at 12 mo.

Pts were stratified according to age at diagnosis, PSA (total, density & nadir), testosterone, dynamic MRI staging, % of positive cores and length of tumor on the diagnosis biopsy.

Secondary objectives were number of pts with GS equal or superior than 7, progression over time of disease clinical symptoms (IPSS score), tumor radiological progression by dynamic MRI, PSA progression, HAD Scale (anxiety) and International Index of Erectile Function (IIEF-5).

RESULTS: 115 eligible men from 22 sites were randomized in arm A (58 pts) & arm B (57 pts). The number of negative biopsies at 12 mo was statistically different (p=0.03) between arm A (28 (53%)) & arm B (17 (32%)). Among the secondary endpoints, the arm A strategy statistically improved outcome on: IPSS at 9 mo, PSA reduction at 3, 6 & 9 mo. Moreover, at 12 mo IIEF-5 score was not statistically different between the 2 arms. Other endpoints points were not significantly improved. No serious adverse events related to the study drug were observed.

CONCLUSIONS: Results obtained with 3mo of Leuprorelin for LRPC suggest that ADT can be used to reverse LRPC lesions, hence improving the results obtained with subsequent AS. Early ADT led to a better quality of life at 9 months. This strategy also allows detecting hidden aggressive disease.

**Source of Funding:** Takeda

## LBA19

### THE MEN'S EATING AND LIVING (MEAL) STUDY (CALGB 70807 [ALLIANCE]): A RANDOMIZED CLINICAL TRIAL OF A DIET INTERVENTION IN MEN ON ACTIVE SURVEILLANCE FOR PROSTATE CANCER

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INTRODUCTION AND OBJECTIVES: Diet modifies the risks of prostate cancer incidence and progression. We tested the efficacy of a high-vegetable diet to prevent clinical progression in prostate cancer patients on active surveillance

METHODS: In the Men's Eating and Living (MEAL) Study (CALGB 70807 [Alliance]), we randomized (1:1) eligible participants to a telephone-based, validated diet counseling intervention promoting vegetable intake or to a control condition for 2 years. Eligibility criteria included age 50 to 80 years; biopsy-proven adenocarcinoma of the prostate; diagnosis $\leq$ 24 months prior to presentation with $\geq$ 10-core prostate biopsy in which $<$ 25% of the total number of cores and $\leq$ 50% of any single core contained cancer; Gleason sum $\leq$ 6 for men $\leq$ 70 years and Gleason sum $\leq$ (3 + 4) = 7 for men $>$ 70 years; clinical stage $\leq$ T2a; and serum PSA $<$ 10 ng/mL. Randomization was stratified by age ($>$ 70 years vs. $\geq$ 70 years), race (African American vs. Other) and time since diagnostic biopsy (0-12 months vs. $>$ 12 and $\leq$ 24 months). The primary outcome was clinical progression defined as serum prostate-specific antigen (PSA) $\geq$ 10 ng/mL, PSA doubling time (PSADT) $<$ 3 years, or pathological progression on follow-up biopsy. The primary endpoint was time to progression (TTP), defined as the length of time from the date of random assignment to clinical progression; patients who died from any cause without experiencing progression were censored at the time of death and patients who elected to pursue treatment despite not meeting the criteria for progression were censored at the time of withdrawal. The primary analysis will be based on all randomized patients, but exclude those patients who later became ineligible by centralized pathology review of their baseline tissue specimens. Secondary outcomes included the incidence of definitive treatment for prostate cancer.

RESULTS: From 2011 to 2015, 478 (103%) of a targeted 464 patients were randomized at 91 study sites. Final results for the primary and secondary outcomes comparing intervention to control will be presented.

CONCLUSIONS: The MEAL Study is the first national, multi-institutional phase III clinical trial of a diet intervention for prostate cancer. These results may substantially inform clinical care of prostate cancer patients.

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## LBA20

### MRI-GUIDED TRANSURETHRAL ULTRASOUND ABLATION (TULSA) IN PATIENTS WITH LOCALIZED PROSTATE CANCER: PRELIMINARY RESULTS OF TACT PIVOTAL STUDY

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INTRODUCTION AND OBJECTIVES: MRI-guided transurethral ultrasound ablation (TULSA) is a minimally-invasive technology for ablation of benign and malignant prostate tissue. The