# P007 Feasibility study of a randomised controlled trial of aspirin and/or vitamin D3 for men with early prostate cancer on active surveillance with Prolaris® testing

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**Introduction & Objectives:**

Active Surveillance (AS) delays/avoids radical treatment of early prostate cancer (PCa) patients to minimize therapy-related toxicities whilst maintaining favourable oncological outcomes. Minimally-toxic “adjunctive” oral drug therapies given after diagnosis, and directed by biomarkers, may prevent disease progression and increase AS adherence. The objective of this study was to assess the feasibility of a randomised controlled trial (RCT) of aspirin and/or vitamin D3 in AS low/favourable intermediate risk PCa patients with Prolaris® testing.

**Materials & Methods:**

Patients aged >16 years with newly-diagnosed low or favourable intermediate risk (PSA ≤ 15 ng/ml, International Society of Urological Pathology (ISUP) Grade Group ≤2, maximum biopsy core length <10 mm, clinical stage ≤cT2c) were enrolled into a multi-centre randomised, double-blind, placebo-controlled study (ISRCTN91422391, NCT03103152). Participants were randomised to oral low dose (100 mg), standard dose (300 mg) aspirin or placebo and/or vitamin D3 (4000 IU) versus placebo in a 3 x 2 factorial design with biopsy tissue Prolaris® testing. The primary endpoint was trial acceptance/entry rates. Secondary endpoints included feasibility of Prolaris® testing, 12-month disease re-assessment (imaging/biochemical/histological), and 12-month treatment adherence/safety.

**Results:**

104 (80%) accepted recruitment from seven sites over 12 months, of which 94 patients represented the per protocol population receiving treatment. Prolaris® testing was performed on 76/94 (81%) diagnostic biopsies. Twelve-month disease progression rate was 43.3%. Of all participants, 68.1% (64/94) returned their medication packages for treatment compliance assessment by local trial pharmacy teams at 6 months and 64.5% (49/76) at 12 months. Assessable 12-month treatment adherence in non-progressing patients to aspirin and vitamin D across all treatment arms was 91%. Two drug-attributable serious adverse events in 1 patient allocated to aspirin were identified. The study was not designed to determine differences between treatment arms.

**Conclusions:**

Recruitment of AS PCa patients into a multi-centre multi-arm placebo-controlled RCT of minimally-toxic adjunctive oral drug treatments with molecular biomarker profiling is acceptable and safe. A larger phase III study is needed to determine optimal agents, intervention efficacy, and outcome-associated biomarkers.