Interruption androgen deprivation therapy can only be appropriately evaluated in a randomized fashion. We present updated follow up results, to Sept 2016, from the SEUG 9901 Phase III study comparing the intermittent monotherapy with continuous combined androgen deprivation using an LHRH analogue and ciproterone acetate and associated components of quality of life.

Patients with advanced prostatic cancer and M1, received Cypredronol Acetate (200 mg/day) administered for 2 weeks. LHRH agonist (1 monthly depot injection) is started when the PSA is below 4 ng/ml, patients where randomised between continuous therapy LHRH plus CPA (200 mg/day) and intermittent therapy CPA (300 mg/day).

Follow up has been extended to a maximum of 15 years and 20% of patients are still in active follow up. There is no evidence that an initial treatment with intermittent therapy is harmful to patients in that overall survival is poorer. If anything, survival is poorer on continuous therapy driven largely by elevated cardio vascular deaths. There is no difference in prostate cancer deaths, though those randomized to intermittent therapy have a greater hazard of a death due to a non-prostate cancer.

**RESULTS**

1045 men with a median PSA of 15.9ng/ml were registered between October 1999 and September 2007. 24.5% of registered patients have a PSA less than 10ng/ml; 39.5% of registered patients have a PSA greater than 20ng/ml. 90.3% have a T3 tumour and 5.6% T4; only 14% have metastatic prostate cancer, 63% have Gleason Score 6-7 and 21% Gleason 8+918 patients (aged 44-81, mean 72) have been randomized 462 to Intermittent therapy and 456 to Continuous. The median PSA at randomisation is 1.0 ng/ml. The maximum follow up is 15.6 years with a median of 5.8 years. 630 (310 Intermittent, 320 Continuous) patients have died; 200 from prostate cancer (100 Intermittent and 100 Continuous), 267 from CVD (125 Intermittent and 142 Continuous), 43 from other metastatic disease (27 Intermittent and 16 Continuous) 120 from Other Causes, including unknown cause (58 Intermittent and 62 Continuous). Median survival is 6.5 years (95% CI 6.0, 6.9) and 535 patients have been followed up for at least five years, with 361 for at least 7 years and 195 for at least 10 years (22% of those randomized to intermittent therapy and 21% of those on continuous). Metastatic status, PSA at randomisation and age at randomization are all prognostic factors for survival. M1 patients have an increased risk of dying (HR=1.67, 95% CI 1.30, 2.13) and there is a trend for an increasing hazard of death with increasing age so that men aged 75+ have a hazard ratio of 1.73 (95% CI 1.16, 2.57) compared to men aged under 60. Men whose PSA falls to between 2 and 4 have an increased hazard of dying relative to those whose PSA falls below 0.5 (HR=1.88, 95% CI 1.53, 2.30). There was no evidence that T Stage (p=0.76) or Gleason score (p=0.09) are associated with a death due to a non-prostate cancer.

Adjusting for Age, PSA and metastatic status, patients on continuous therapy had an elevated hazard of death, HR=1.13 (95% CI 0.97, 1.32), p=0.13, Figure 1. The hazard of a CVD death is HR=1.22 (95% CI 0.96, 1.55; p=0.11), Figure 2, while for other metastatic disease it is HR = 0.64(95% CI 0.35, 1.19, p = 0.16), Figure 3. For Prostate cancer HR = 1.08 (95% CI 0.82, 1.34, p = 0.57), Figure 4, and for other causes of death it is HR = 1.18 (95% CI 0.82, 1.70, p = 0.36), Figure 5.

**CONCLUSIONS**

Follow up has been extended to a maximum of 15 years and 20% of patients are still in active follow up. There is no evidence that an initial treatment with intermittent therapy is harmful to patients in that overall survival is poorer. If anything, survival is poorer on continuous therapy driven largely by elevated cardio vascular deaths. There is no difference in prostate cancer deaths, though those randomized to intermittent therapy have a greater hazard of a death due to a non-prostate cancer.

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**INTRODUCTION & OBJECTIVES**

Intermittent androgen deprivation therapy can only be appropriately evaluated in a randomized fashion. We present updated follow up results, to Sept 2016, from the SEUG 9901 Phase III study comparing the intermittent monotherapy with continuous combined androgen deprivation using an LHRH analogue and ciproterone acetate and associated components of quality of life.

**MATERIAL & METHODS**

Patients with advanced prostatic cancer and M1, received Cypredronol Acetate (200 mg/day) administered for 2 weeks. LHRH agonist (1 monthly depot injection) is started when the PSA is below 4 ng/ml, patients where randomised between continuous therapy LHRH plus CPA (200 mg/day) and intermittent therapy CPA (300 mg/day).