**7015** POSTER

**Degarelix versus leuprolide in patients with metastatic prostate cancer: assessment of serum alkaline phosphatase over time**

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**Background:** In a randomised, open-label, parallel-group, phase III trial (CS21), the new GnRH blocker, degarelix, was as effective as leuprolide at suppressing testosterone to ⩽0.5 ng/mL in >95% of prostate cancer (PCa) patients over a 1-year treatment period. Here we report serum alkaline phosphatase (S-ALP) as a marker of extent of skeletal metastases.
**Material and Methods:** Patients with histologically confirmed PCa (all stages), were recruited. 610 patients (mean age 72 years, median PSA 19.0 ng/mL) were randomised to 1 of 3 regimens: degarelix s.c. 240 mg for 1 month (initiation dose) followed by monthly maintenance doses of 80 mg (n = 207) or 160 mg (n = 202), or i.m. leuprolide depot 7.5 mg/month (n = 201). Patients receiving leuprolide could also receive an antiandrogen. Results of S-ALP analyses for the degarelix 240/80 mg (approved dose) and leuprolide groups in patients with: 1) Baseline metastatic PCa as verified by bone scan, and 2) Baseline PSA >50 ng/mL are presented. A repeated measures analysis (all time points from Day 112) with treatment and day as factors and baseline value as covariate, as well as values at the end of the study (Day 364) were used to assess between-treatment differences.
**Results:** Baseline S-ALP levels were high in metastatic patients. In metastatic disease, after initial peaks in both groups, S-ALP levels were suppressed below baseline with degarelix but were maintained around baseline with leuprolide. The rise in S-ALP with leuprolide late in the study, indicating therapy failure, was not observed with degarelix. The same pattern of S-ALP response was seen in patients with baseline PSA ⩾50 ng/mL.

| | Degarelix 240/80 mg (n = 207) | | | | | Leuprolide 7.5 mg (n = 201) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | S-ALP values (IU/L) [unadjusted means] | | | | | S-ALP values (IU/L) [unadjusted means] | | | | |
| | N | Baseline | Day 112 | Day 224 | Day 364 | N | Baseline | Day 112 | Day 224 | Day 364 |
| Metastatic disease | 37 | 203 | 104[a] | 84 | 96[c] | 47 | 148 | 125[a] | 97 | 179[c] |
| Baseline PSA ⩾50 ng/mL | 48 | 166 | 95[b] | 73 | 83[d] | 55 | 148 | 114[b] | 89 | 163[d] |

Between-treatment differences from Day 112 to 364 ([a]p = 0.1412 and [b]p = 0.1237) and at Day 364 ([c]p = 0.0137 and [d]p = 0.0073)

**Conclusions:** Patients with metastatic disease or those with PSA levels ⩾50 ng/mL at baseline experienced greater reductions in S-ALP with degarelix than leuprolide. Patients in the degarelix group maintained a suppressed S-ALP throughout the study and did not display the signs of therapy failure, as seen for the leuprolide patients. Results suggest better control of skeletal metastases with degarelix than leuprolide.
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**7016** POSTER

**Degarelix versus leuprolide in prostate cancer patients: new prostate-specific antigen data from a phase III trial (CS21)**

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**Background:** A randomised, open-label, parallel-group, phase III trial (CS21) demonstrated that the new GnRH blocker, degarelix, was non-inferior to leuprolide at suppressing testosterone to castrate levels over a 1-year treatment period (95–98% response). Here we report PSA data by subgroup according to disease stage and PSA level at baseline.
**Materials and Methods:** Patients with histologically confirmed prostate cancer (all stages) were randomised to 1 of 3 dosing regimens: leuprolide 7.5 mg/month (n = 201) or degarelix s.c. starting dose of 240 mg for 1 month and thereafter monthly maintenance doses of 80 mg (n = 207) or 160 mg (n = 202). Antiandrogen flare protection could be given in the leuprolide group. Here we report data for degarelix 240/80 mg (the approved dose for the treatment of advanced prostate cancer) vs leuprolide.
**Results:** Overall, 610 patients (mean age 72 years; median testosterone 3.93 ng/mL; median PSA 19.0 ng/mL) were treated. 31.3% of patients had localised, 29.2% had locally advanced and 20.5% had metastatic prostate cancer (19% incompletely classified). At Day 3, median testosterone levels were 0.24 ng/mL vs 6.3 ng/mL in the degarelix and leuprolide groups ($p < 0.001$). Median PSA reductions on Days 14 (64% vs 18%) and 28 (85% vs 68%) were significantly greater with degarelix 240/80 mg compared with leuprolide ($p < 0.001$). Overall, PSA failure (2 consecutive increases in PSA level of 50% and ⩾5 ng/mL compared with nadir) occurred in 8.9% vs 14.1% of patients receiving degarelix and leuprolide during the 1-year treatment period. PSA failure occurred more often in patients with metastatic disease and higher baseline PSA level across both treatment groups (Table). In the subgroup of patients with baseline PSA ⩾20 ng/mL, time to PSA failure was significantly longer for patients receiving degarelix ($p = 0.0436$).

| | Degarelix 240/80 mg (n = 207) | | Leuprolide 7.5 mg (n = 201) | |
|---|---|---|---|---|
| | N | PSA failure, n (%) | N | PSA failure, n (%) |
| Disease stage | | | | |
| Localised | 69 | 0 | 63 | 2 (3.2) |
| Locally advanced | 64 | 7 (10.9) | 52 | 6 (11.5) |
| Metastatic | 37 | 8 (21.6) | 47 | 17 (36.2) |
| Incomplete classification | 37 | 1 (2.7) | 39 | 1 (2.6) |
| Baseline PSA, ng/mL | | | | |
| <10 | 55 | 0 | 64 | 0 |
| 10–20 | 52 | 0 | 44 | 0 |
| 20–50 | 52 | 2 (3.9) | 38 | 4 (10.5) |
| ⩾50 | 48 | 14 (29.2) | 55 | 22 (40.0) |

**Conclusions:** Degarelix 240/80 mg induced a fast testosterone and PSA suppression. PSA failure occurred more often in patients with metastatic disease or baseline PSA ⩾20 ng/mL; the latter group experienced significantly longer time to PSA failure with degarelix compared with leuprolide.
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**7017** POSTER

**Quality of life, five years after I-125 brachytherapy for localised prostate cancer**

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**Background:** Patients with localised prostate cancer who choose permanent brachytherapy as their treatment option should be informed about their quality of life (QoL) after treatment. Therefore the 5 years QoL results derived from the Expanded Prostate Cancer Index Composite (EPIC) are presented here.
**Methods:** In 2002 and 2003 150 patients who were treated with I-125 brachtherapy alone were invited to register their urinary, bowel, sexual and hormonal function pre treatment and at regular time intervals thereafter. A well validated questionnaire (EPIC) was used. 126 patients participated. The 2 years results were described and published in 2007. In 2008, five years after treatment, the same 126 patients were send further questionnaire which was returned by 94 patients (75%).
**Results:** Previous analysis in 2007 showed a maximum detoriation in mean urinary and sexual EPIC score 4–6 weeks after implant, thereafter it steadily improved. The urinary function returned to pre treatment levels at 12 months. Subsequent analysis five years after treatment showed no difference in mean summary for urinary, bowel, and hormonal EPIC scores between pre treatment and five years after treatment. The same observation was noticed for the subscales (function and bother). In contrast the mean sexual summary and the subscales sexual function and bother improved in time, but never returned to pre treatment levels. Age is a significant independent predicting factor for sexual summary and the subscale function at all time points ($p < 0.001$) but not for the subscale bother.
**Conclusion:** Except for sexual function there is no difference in urinary, bowel and hormonal function five years after treatment compared with their function before implant. The sexual function didn't improve further beyond the 12 months after I-125 implant. Age is a significant independent predicting factor for sexual function but in time patients seem to be less bothered about their decreased function.