Early Effect of Alendronate or Raloxifene Treatment in Osteoporotic Women Monitored by Multi-Site QUS

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The most common anti-resorbing or anti resorptive agents used for treatment of osteoporosis are Alendronate (ALN) and Raloxifene (RLX). Currently, treatment monitoring may include evaluation of markers of bone turnover 3 months after the initiation of treatment and BMD measurements by DXA after at least 12 months.

This study evaluates the hypothesis that QUS device (Sunlight Omnisense™), which depends on bone characteristics such as density, geometry and elasticity will be capable of detecting early bone response to treatment with ALN or RLX.

One hundred and ninety six osteoporotic women with Speed of Sound (SOS) T-score less than –2.0 at least at one skeletal site, were enrolled in a prospective follow up study. Patients were assigned to treatment according to physicians' decision; 125 to ALN and 71 to RLX. SOS measurements were performed at 4 skeletal sites at baseline, and after 6, 9 and 12 months. We currently report the 6 months interim data.

	Radius	**Phalanx**	**Tibia**	**Metatarsus**
Alendronate (N= 51)	N= 27*	N= 36*	N= 23*	N= 14*
Baseline (T-score)	-3.37	-3.10	-3.19	-2.63
6 Months (T-score)	-2.93	-2.96	-3.05	-2.39
Difference (SE)	0.44 (0.14)†	0.14 (0.07) †	0.14 (0.12)	0.24 (0.16)
Pos. change (sig. Change**)	21 (13)	23 (9)	15 (7)	9 (5)
Raloxifene (N =20)	N=9*	N=7*	N=5*	N=5*
Baseline (T-score)	-3.12	-3.05	-3.73	-2.59
6 Months (T-score)	-3.04	-2.53	-3.08	-1.86
Difference (SE)	0.08 (0.24)	0.52 (0.23) †	0.65 (0.24) †	0.73 (0.53)

*Women with T -score <-2.0 at this specific site, **Significant change > 1.8CV, †p-value < 0.05

On the individual level, 80% of patients with low baseline Radius SOS experienced positive change, of whom 62% experienced significant increase. Comparable changes in T-score were previously reported using BMD as a surrogate for bone response to treatment (an increase of 0.21-0.33 T-score with ALN or RLX respectively after the first year of treatment).
Conclusion: Significant increase in SOS measured by the Omnisense at two out of four skeletal sites induced by ALN are detectable as early as 6 months after initiation of treatment. SOS increase is also observed with RLX treatment, though number of patients is too small to warrant a conclusion yet. The two therapies probably affect bone characteristics such as porosity and cortical thickness at a different rate in different skeletal sites. This could explain the site-to-site discordance between the results, as the SOS measurement depends on the various bone parameters.

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