**Effect of rituximab on a salivary gland ultrasound score in primary Sjögren’s syndrome: results of the TRACTISS randomised double-blind multicentre sub-study**

*Benjamin A. Fisher1,2,3, Colin C Everett 4, John Rout5, John L O’Dwyer 6, Paul Emery 7, Costantino Pitzalis 8, Wan-fai Ng 9, Andrew Carr10, Colin T Pease 7, Elizabeth J Price 11, Nurhan Sutcliffe 12, Jimmy Makdissi13, Anwar R Tappuni13, Nagui ST Gendi14, Frances C Hall 15, Sharon P Ruddock 4, Catherine Fernandez 4, Claire T Hulme 6, Kevin A Davies 16, Christopher J Edwards 17, Peter C Lanyon 18, Robert J Moots19, Euthalia Roussou20, Andrea Richards5, Linda D Sharples21, Michele Bombardieri 8 and Simon J Bowman 1,2,3*

Online Supplementary Table S1. Selected baseline characteristics of subjects consenting and not-consenting to the salivary gland ultrasound (SGUS) substudy.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | Did not consent (n=67) | Consented to SGUS substudy (n=66) | All (n=133) |
| Age (Years) | | 52.8 (11.24) | 56.0 (11.66) | 54.4 (11.5) |
| Years since diagnosis | | 6.1 (5.82) | 5.4 (4.92) | 5.7 (5.4) |
| 10 or more years since diagnosis: n (%) | | 14 (20.9) | 10 (15.2) | 24 (18.0) |
| Female Sex: n (%) | | 62 (92.5) | 62 (93.9) | 124 (93.2) |
| Current Medications (prior to randomisation) | |  |  |  |
|  | Pilocarpine: n (%) | 5 (7.6) | 9 (13.4) | 14 (10.5) |
|  | Hydroxychloroquine: n (%) | 34 (51.5) | 40 (59.7) | 74 (55.6) |
|  | Corticosteroids: n (%) | 8 (12.1) | 11 (16.4) | 19 (14.3) |
|  | NSAIDS: n (%) | 15 (22.7) | 20 (29.9) | 35 (26.4) |
| Unstimulated Salivary Flow (mL/15min) | | 1.1 (1.25) | 1.2 (1.77) | 1.2 (1.52) |
| Stimulated salivary flow (mL/10min) | | 3.4 (4.10) | 3.5 (4.43) | 3.4 (4.26) |
| IgG (g/L) | | 18.8 (8.19) | 17.2 (6.8) | 18.0 (7.5) |
| IgA (g/L) | | 3.2 (1.33) | 3.2 (1.98) | 3.2 (1.7) |
| IgM (g/L) | | 1.1 (0.52) | 1.3 (0.71) | 1.2 (0.6) |
| Anti-Ro autoantibody positive | | 67 (100.0) | 65 (98.5) | 132 (99.2) |
| Reduced C4 | | 9 (13.4) | 10 (15.2) | 19 (14.3) |
| Visual Analogue Scales (Average over last 2 weeks, mm. 100=Severe, except Global) | |  |  |  |
|  | Fatigue | 71.7 (16.37) | 74.0 (15.87) | 72.8 (16.1) |
|  | Oral Dryness | 74.0 (14.61) | 78.6 (17.43) | 76.3 (16.2) |
|  | Ocular Dryness | 65.0 (20.20) | 76.4 (18.68) | 70.7 (20.2) |
|  | Overall Dryness | 72.2 (14.07) | 78.3 (17.00) | 75.2 (15.8) |
|  | Joint Pain | 50.7 (28.32) | 58.8 (27.26) | 54.7 (28.0) |
|  | Global Assessment (100=PSS very active) | 68.1 (17.27) | 71.2 (18.47) | 69.7 (17.9) |
| ESSPRI (10=Maximal Symptom Severity) | | 6.7 (1.71) | 6.5 (1.57) | 6.6 (1.6) |
| ESSDAI (123=Maximal Disease Activity) | | 5.6 (5.10) | 5.7 (3.91) | 5.7 (4.52) |

Footnote: Values are Mean and standard deviation unless otherwise stated

Online Supplementary Table S2. Odds of rituximab improving the individual domains of the Total Ultrasound Score were modelled by repeated measures logistic regression, including baseline score, age, disease duration and time-point.

|  |  |  |
| --- | --- | --- |
| Domain | Week 16 | Week 48 |
| Echogenicity | 0.20  (0.02, 2.8)  *p=0.23* | 1.89  (0.21, 17.34  *p=0.57* |
| Consistency | 5.09  (0.85, 30.50)  *p=0.07* | 4.88  (0.69, 34.33)  *p=0.11* |
| Definition | 6.76  (1.06, 42.98)  ***p=0.04*** | 10.31  (1.00, 105.89)  ***p=0.05*** |
| Glands involved | - | 4.98  (0.47, 53.02)  *p=0.18* |
| Hypoechoic foci size | 0.46  (0.05, 4.64)  *p=0.51* | 1.80  (0.23, 13.98)  *p=0.57* |

Footnote: Values are odds ratios (95% confidence interval)