



POSTER PRESENTATION

Open Access

PReS-FINAL-2134: Assessment of radiographic progression in patients (pts) with systemic juvenile idiopathic arthritis (sjia) treated with tocilizumab (TCZ): 2-year results from the tender trial

C Malattia¹, N Ruperto¹, E Palmisani¹, S Pederzoli¹, A Pistorio¹, HI Brunner², R Cuttica¹, I Calvo¹, SM Garay¹, D Eleftheriou¹, C Wouters¹, J Wang³, C Devlin³, D Lovell², A Martini¹, F De Benedetti⁴, A Ravelli^{1*},
PRCSG and PRINTO

From 20th Pediatric Rheumatology European Society (PReS) Congress
Ljubljana, Slovenia. 25-29 September 2013

Introduction

A phase 3 trial (TENDER) demonstrated the efficacy of the interleukin-6 receptor inhibitor TCZ in pts with sjia [1,2].

Objectives

To investigate progression of radiographic joint damage in pts with sjia treated with TCZ for up to 2 years in TENDER.

Methods

112 pts 2-17 yrs old with active, refractory sjia of ≥ 6 months' duration and inadequate response to previous non-steroidal anti-inflammatory drugs and oral corticosteroids were enrolled in TENDER. Pts were randomised 2:1 to receive TCZ according to body weight (12 mg/kg < 30 kg or 8 mg/kg ≥ 30 kg) or placebo IV every 2 wks for 12 wks. Pts then received open-label TCZ in the ongoing long-term extension. Radiographic progression was calculated as change in adapted Sharp/van der Heijde score (ash) score and/or Poznanski score, assessed on hand and wrist radiographs, from baseline to wks 52 and 104. Radiographic progression was indicated by a positive ash score change or negative Poznanski score change. Clinical efficacy endpoints included American College of Rheumatology (ACR) Paediatric (Pedi) 70/90 responses.

Results

Baseline and ≥ 1 postbaseline ash and Poznanski scores were available for 47 and 33 pts, respectively (reasons for missing x-rays: early withdrawal, no consent, unreadable x-rays). Baseline characteristics for pts with radiographic data were similar to the whole TCZ population [1]. Pts with assessable ash/Poznanski scores had 5.2/4.8-yr disease duration, 21.3/19.2 active joints, 20.0/18.2 joints with limitation of movement and erythrocyte sedimentation rates of 53.9/59.2 mm/h. At wks 52 and 104, 20 and 19 pts, respectively, had ash progression, and 8 and 6 pts, respectively, had Poznanski score progression. Median change in ash score from baseline to wks 52 and 104 were 0 and 0.5, respectively (Table). Median change in Poznanski score from baseline to wks 52 and 104 were 0.3 and 0.17, respectively (Table 1).

Conclusion

Though changes in radiographic scores over time were seen in many pts, on average, pts with sjia did not experience

Table 1

	Wk 52	Wk 104
Ash score (n = 47), median (IQR)	0.00 (-8.70: 4.00)	0.50 (-7.50: 12.00)
Poznanski score (n = 33), median (IQR)	0.30 (-0.02: 1.03)	0.17 (0.01: 1.04)
ACR Pedi 70 (n = 112), n/N (%)	92/106 (86.8)	57/65 (87.7)
ACR Pedi 90 (n = 112), n/N (%)	67/106 (63.2)	46/65 (70.8)

¹PRINTO, Genoa, Italy

Full list of author information is available at the end of the article

noticeable progression of radiographic damage over 2 yrs of treatment with TCZ.

Disclosure of interest

C. Malattia: None declared., N. Ruperto Grant/Research Support from: Abbott, astrazeneca, BMS, Centocor, Lilly, Francesco Angelini, GSK, Italfarmaco, merckserono, Novartis, Pfizer, Regeneron, Roche, Sanofi Aventis, Schwarz Biosciences, Xoma, Wyeth, Consultant for: Abbott, astrazeneca, BMS, Centocor, Lilly, Francesco Angelini, GSK, Italfarmaco, merckserono, Novartis, Pfizer, Regeneron, Roche, Sanofi Aventis, Schwarz Biosciences, Xoma, Wyeth, Speakers Bureau: Abbott, Boehringer, BMS, Novartis, Astellas, Italfarmaco, medimmune, Pfizer, Roche, E. Palmisani: None declared., S. Pederzoli: None declared., A. Pistorio: None declared., H. I. Brunner Consultant for: Novartis, Genentech, medimmune, EMD Serono, AMS, Pfizer, UCB, Janssen, Speakers Bureau: Genentech, R. Cuttica Speakers Bureau: Roche, Abbott, Pfizer, Novartis, BMS, I. Calvo: None declared., S. M. Garay: None declared., D. Eleftheriou: None declared., C. Wouters: None declared., J. Wang Employee of: Roche Products Ltd, C. Devlin Employee of: Roche Products Ltd, D. Lovell Grant/Research Support from: NIH, Consultant for: astrazeneca, Centocor, Janssen, Wyeth, Amgen, Bristol-Meyers Squibb, Abbott, Pfizer, Regeneron, Hoffmann-La Roche, Novartis, Genentech, Speakers Bureau: Roche, Genentech, A. Martini Grant/Research Support from: Abbott, astrazeneca, BMS, Centocor, Lilly, Francesco Angelini, GSK, Italfarmaco, merckserono, Novartis, Pfizer, Regeneron, Roche, Sanofi Aventis, Schwarz Biosciences, Xoma, Wyeth, Consultant for: Abbott, astrazeneca, BMS, Centocor, Lilly, Francesco Angelini, GSK, Italfarmaco, merckserono, Novartis, Pfizer, Regeneron, Roche, Sanofi Aventis, Schwarz Biosciences, Xoma, Wyeth, Speakers Bureau: Abbott, Boehringer, BMS, Novartis, Astellas, Italfarmaco, medimmune, Pfizer, Roche, F. De Benedetti Grant/Research Support from: Abbott, Pfizer, BMS, Roche, Novimmune, Novartis, SOBI, A. Ravelli: None declared.

Authors' details

¹PRINTO, Genoa, Italy. ²PRCSG, Cincinnati, USA. ³Roche, Welwyn, UK. ⁴IRCCS Ospedale Ped Bambino Gesù, Rome, Italy.

Published: 5 December 2013

References

1. De Benedetti F, et al: *N Engl J Med* 2012, **367**:2385.
2. De Benedetti F, et al: *Ann Rheum Dis* 2012, **71**(Suppl 3):425.

doi:10.1186/1546-0096-11-S2-P147

Cite this article as: Malattia et al.: PReS-FINAL-2134: Assessment of radiographic progression in patients (pts) with systemic juvenile idiopathic arthritis (sja) treated with tocilizumab (TCZ): 2-year results from the tender trial. *Pediatric Rheumatology* 2013 **11**(Suppl 2):P147.

Submit your next manuscript to BioMed Central and take full advantage of:

- Convenient online submission
- Thorough peer review
- No space constraints or color figure charges
- Immediate publication on acceptance
- Inclusion in PubMed, CAS, Scopus and Google Scholar
- Research which is freely available for redistribution

Submit your manuscript at
www.biomedcentral.com/submit

