



POSTER PRESENTATION

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Pharmacovigilance in juvenile idiopathic arthritis patients (Pharmachild) treated with biologic agents and/or methotrexate. Consolidated baseline characteristics from Pharmachild and other national registries

Joost Swart^{1*}, Alessandro Consolaro², Gerd Horneff³, BIKER, Kimme L Hyrich⁴, UK BCRD Study Group and BSPAR Etanercept Study Group, Francesca Bovis², Jose Melo-Gomes², Ekaterina Alexeeva², Stefano Lanni², Gerd Ganser⁵, Violeta Panaviene², Jordi Anton², Ivan Foeldvari⁶, Valda Stanevicha², Susan Nielsen², Ralf Trauzeddel⁷, Constantin Ailioaie², Pierre Quartier², Toni Hospach⁸, Gordana Susic², Maria Trachana², Frank Weller-Heinemann⁹, Alberto Martini², Nico Wulffraat², Nicolino Ruperto²

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Introduction

The availability of methotrexate (MTX) and biological agents has provided a major change in the treatment of children with juvenile idiopathic arthritis (JIA). An international registry named Pharmachild (European Union grant 260353) has been set up by the Pediatric Rheumatology International Trials Organisation (PRINTO)/Pediatric Rheumatology European Society (PRES). In parallel several national registries with the same purpose have been set up in different European Countries for the follow-up of these patients.

Objectives

To evaluate the possibility to combine data coming from different national registries in order to assess the long-term safety.

Methods

We merged into a unified database the baseline demographic data of JIA patients treated with MTX or biolo-

gicals coming from the Pharmachild registry and from the national registries of Germany, United Kingdom and Portugal. Data are presented as frequencies (%) or medians with 1st and 3rd quartiles.

Results

About 63% of the patients has been treated with biologics alone or in combination with MTX, and 29% only with MTX. The events of special interest (ESI) ranged from 4.5 to 15.0% and the other moderate/severe/serious adverse events (AE) from 13.1% to 69.9%. Table 1.

Conclusion

Combination of information from different data sources is a recommended task and will provide a powerful tool for the future analysis of safety events coming from different registries.

Disclosure of interest

None declared.

¹UMC Utrecht, Utrecht, Netherlands

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Table 1

	Pharmachild (N=5571)	NR UK (N=1537)	NR Germany (N=3243)	NR Portugal (N=112)	TOTAL (N=10463)
Age at onset	5.4 (2.4 – 10.0)	-	7.2 (3.1-11.4)	6.3 (2.5-10.9)	-
Age at JIA Diagnosis	6.2 (2.8 – 11.0)	5.5 (2.1-10.2)	8.2 (4.0-12.3)	7.3 (3.3-12.3)	-
Disease duration at the last follow-up	4.9 (2.5 – 8.2)	5.4 (2.7 – 8.8)	5.2 (3.1-8.4)	3.0 (0.5-9.6)	-
Therapy with MTX only	1365 (24.5)	503 (32.7)	1132/3134 (36.1)	0 (0.0)	3000/10354 (29.0)
Therapy with only one Biologic Drug + MTX	2378 (42.7)	862 (56.1)	1545/3134 (49.2)	27 (24.1)	4812/10354 (46.5)
Therapy with more than one Biologic + MTX	872 (15.6)	141 (9.2)	340/3134 (10.8)	78 (69.6)	1431/10354 (13.8)
Nr. patients with ESI or AE	1070 (19.2)	1093 (71.1)	1163(37.1)	27 (24.1)	3353 (32.4)
Nr. patients with ESI	496 (8.9)	230 (15.0)	249 (7.9)	5 (4.5)	980 (9.5)
Nr. patients with AE	729 (13.1)	1075 (69.9)	1069 (34.1)	24 (21.4)	2897 (28.0)

Authors' details

¹UMC Utrecht, Utrecht, Netherlands. ²Istituto Giannina Gaslini, Genoa, Italy.
³Zentrum für Allgemeine Paediatric und Neonatologie - Asklepios Klinik Sankt Augustin, Sankt Augustin, Germany. ⁴Arthritis Research UK Centre for Epidemiology, University of Manchester, Manchester, UK. ⁵St. Josef-Stif Sendenhorst, Sendenhorst, Germany. ⁶Hamburger Zentrum für Kinder- und Jugendrheumatologie, Hamburg, Germany. ⁷Helios Kliniken Berlin, Berlin.
⁸Olga Hospital, Stuttgart, Germany. ⁹Klinikum Bremen-Mitte, Bremen, Germany.

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