12–17 year-olds	3171	0.70 (0.57, 0.86)	241	0.67 (0.54, 0.83)
Adult Controls	4543	-	361	-

Conclusion Based on these results, children aged 2–11 yrs require a higher mg/kg/day dose of rofecoxib for similar steady-state systemic exposure to adult historical controls receiving 25 mg. Assuming linear dose proportionality, a dose of ~0.6 mg/kg/day in children aged 2–11 yrs, should approximate the exposure of 25 mg in adults and adolescents aged 12–17 yrs showed similar systemic exposure to adults taking identical doses of rofecoxib.

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OP0095 THERAPEUTIC EFFICACY OF MULTIPLE INTRAVENOUS INFUSIONS OF ANTI-TUMOUR NECROSIS FACTOR-ALFA MONOCLONAL ANTIBODY (INFLIXIMAB) IN PERSISTENTLY ACTIVE REFRACTORY JUVENILE IDIOPATHIC (CHRONIC) ARTHRITIS. AN ONE YEAR OPEN PROSPECTIVE PILOT STUDY

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Background

Objectives An open prospective trial was carried out in a young population affected by severe, refractory, polyarthritic JIA to evaluate the efficacy and safety of Infliximab (Remicade).

Methods We enrolled 17 females, median age at the start of the therapy 22.9 yrs (8–33), median onset age 3 yrs (1–16), median disease duration 15.6 yrs (5–31). All patients had been previously treated with more than one DMARD (median number 3.5/patient, as mono or combined therapy). All patients had still active disease: number of active joints (median 5.5), ESR (median 59.5 mm/hr), CRP (median 4.7 mg/dl), physician global evaluation (median VAS 45.5), HAQ (median D. I. 1.13). 14 patients were still on corticosteroids (median 0.11 mg/kg). All patients discontinued any other DMARD aside from s.c. MTX (median weekly dose 15 mg, range 5–25) and continued with previous NSAIDs and corticosteroids. Infliximab was administered as a single infusion of 3 mg/kg at time 0 and at weeks 2, 6, 14, 22, 30.

Results Until now all 17 pts have received the first 2 infusions, 15 pts 3 infusions, 9 pts 6 infusions, 8 pts 7 infusions, 2 pts 8 infusions and 1 pt 10 infusions. One patient withdrew because of a severe adverse event (hypersensitivity reaction at the third infusion). Since the 1st infusion, all 17 patients achieved a very good response (50% reduction in number of active joints, ESR, CRP, VAS). A statistically significant improvement of the following parameters was observed at the 6th infusion assessment (evaluation on 9 patients who completed 30 weeks = 5 months of therapy): the median number of active joints decreased from 5 to 0; ESR decreased from a median of 65 to 23 mm/hr and CRP decreased from a median of 4.6 to 0.4 mg/dl; the median score of the VAS (physician global evaluation) decreased from a 65 to 2. Furthermore after 6 months of therapy we observed a trend to improvement in all scales of SF36 (assessment of the quality of life). An eleven-year-old girl with chronic active uveitis showed a great improvement of the visus.

Conclusion These data suggest that Infliximab can significantly and promptly reduce disease activity and improve the quality of life of patients affected by persistently active and refractory JIA. However more data are needed to evaluate its efficacy and safety as a long-term therapy.

OP0099 MOOD AND STRESSFUL EVENTS PREDICT DAILY FLUCTUATIONS IN DISEASE SYMPTOMS IN JUVENILE POLYARTICULAR ARTHRITIS

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Background Juvenile arthritis is characterised by periods of flare and relative quiescence. Periods of flare are characterised by increased disease activity and worsening symptoms. While the cause of disease flares is unclear, multiple possible triggers have been proposed including infection, trauma, psychosocial stress, and mood.

Objectives The purpose of this study was to examine the relationship of daily mood and daily stressful events to disease symptoms in children with rheumatic disease.

Methods Twenty-four school-aged children (15 girls, 9 boys, mean age 12.4 years) with polyarticular arthritis completed a daily booklet over a two-month period, yielding 1355 total observations. The daily booklet included measures of daily symptoms, function, mood, and stressful events. In addition, we obtained biological measures of disease activity, as well as salivary cortisol levels three times daily. Data were analysed using multi-level random effects modelling in order to take into account both sources of variation in the data set, within-person and between-person. In addition, multilevel models use the number of observations or days rather than the number of participants as the unit of analysis, thus increasing the statistical power.

Results The models indicated that on a day-to-day basis, worse mood and more stressful events were significantly related to increases in daily pain ($p < .0001$ and $p < .02$), fatigue ($p < .0001$ and $p < .02$), and increased interference in social activities ($p < .0001$ and $p < .001$). Worse mood was also related to increases in daily stiffness ($p < .0001$) and to coping, including the ability to control ($p < .0001$) and decrease pain ($p < .0001$).

Conclusion Our data show that day to day fluctuations in mood and stressful events are related to the daily symptoms of children with juvenile polyarticular arthritis and may play a role in the pathogenesis of disease flares. Therefore, interventions aimed at improving mood and stress coping may improve the health status of children with arthritis.

SAT0106 ANTI-TNF-ALPHA THERAPY FOR SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS WITH POLYARTHRITIS

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Background TNF- α antagonism with anti-TNF- α MoAb (Infliximab, Centocor, USA) or soluble TNF- α receptors (Etanercept, Immunex, USA), has emerged as a promising therapeutic tool for refractory chronic arthritis. Both drugs are now licensed for