Phase 4/VDZ/ paediatric IBD/Induction

Outcomes, dosing, and predictors of vedolizumab treatment in children with inflammatory bowel disease (VEDOKIDS):
a prospective, multicentre cohort study

Multicentre, prospective cohort study.

Children age 0-18 years old with IBD who were started on VDZ. VDZ dose 177 mg/m2 body surface (maximum 300 mg)

<u>Primary endpoint</u>: Steroid free and exclusive enteral nutrition-free remission at 14w.

ITT analysis

Results:

- 42% children with UC and 32% of children with CD were in steroid-free and EEN free remission at w14.
- Median drug concentrations were higher in patients with UC than CD, 11.5 vs 5.9, p=0.006
- No severe adverse events reported.

Conclusion:

VDZ showed good safety and effectiveness at inducing remission in children with IBD at 14w, especially in those with UC. In children who weigh less than 30 kg, VDZ should be dosed by child's body surface area (200mg/m2) or weight(10mg/kg)

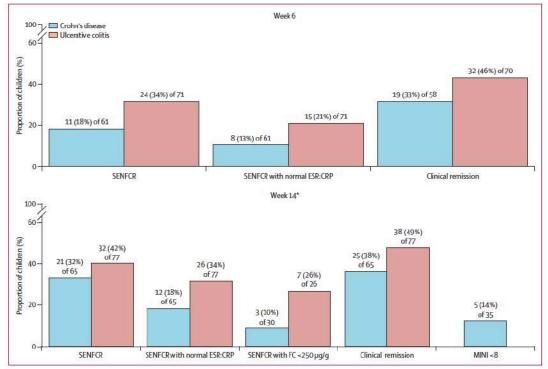


Figure 1: Disease outcomes at weeks 6 and 14

Clinical remission defined as Pediatric Ulcerative Colitis Activity Index less than 10 or weighted Pediatric Crohn's Disease Activity Index less than 12.5. Normal ESR:CRP=CRP less than 0-5 mg/dL and ESR less than 2.5 mm/h. CRP=C-reactive protein. ESR=erythrocyte sedimentation rate. FC=faecal calprotectin. MINI=Mucosal Inflammation Non-Invasive Index. SENFCR=steroid-free and exclusive enteral nutrition-free clinical remission. *Primary outcome.

