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Refid: 12, Skateboards: Are they really perilous? A retrospective study from a district hospital.
Rethnam U, Yesupalan RS, Sinha A.

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Comparative Effectiveness of Pharmacologic Therapies for the Management of Crohn's Disease
Outcomes Form

Please complete this form for RCTs and cohort studies. Submit one form per relevant outcome.

1. If reporting on an efficacy outcome, then choose one category:

[Select an Answer ▾]

KQ1, KQ2, KQ4

Outcome of interest **(Select one response)**	Definition **(Select one response)**	Timing **(Select one response and then specify time in weeks. If more than 1 time point in each group, select the last time point. <u>Be sure to subtract the run-in period</u>.)**
○ CDAI ○ PCDAI ○ HBI ○ Other index (specify): [____] Clear Response	[Select an Answer ▾]	[Select an Answer ▾]
○ Perianal disease Clear Response	[Select an Answer ▾]	[Select an Answer ▾]
○ Health-related quality of life Clear Response	[Select an Answer ▾]	[Select an Answer ▾]
○ Endoscopic healing Clear Response	[Select an Answer ▾]	[Select an Answer ▾]
○ Reduction of steroids ○ Steroid free ○ Number of hospitalizations ○ Need for surgery Clear Response	Define (for reduction of steroids): [____]	[Select an Answer ▾]

KQ3

Outcome of interest **(Select one response)**	Definition **(Select one response)**	Timing **(Select one response and then specify time in weeks. If more than 1 time point in each group, select the last time point.)**	Indicate the population for this analysis **(Select one response)**
○ Mortality ○ Lymphoma ○ Cervical cancer ○ Other cancers (including colon cancer) ○ Serious infections ○ TB ○ Other infections ○ Infusion and injection-site reactions ○ Bone fracture ○ Height ○ Weight Clear Response	○ Define: [____] ○ Not specified Clear Response	[Select an Answer ▾]	[Select an Answer ▾]

Answer Q23-25 for adverse events (KQ3) only. Otherwise, skip to Tables.

21. Was the mode of adverse event collection active or passive? **(Select one response)**
Active ascertainment of harms indicates
a) that participants are asked about the occurrence of specific harms in structured questionnaires or interviews or pre-defined laboratory or diagnostic tests, usually performed at pre-specified time intervals.
b) that the potential occurrence of harmful events are collected at pre-specified intervals; for example, the occurrence of post-operative complications were evaluated on a daily basis within 30 days of the surgery.
These events are potentially expected harms as a result of the intervention.

[Select an Answer ▾]

22. Did the study specify frequency and timing of adverse event collection? **(Select one response)**

[Select an Answer ▾]

23. **If RCT, answer Q25. Otherwise, skip to Tables.**

Was the analysis for this outcome "Intention-to-treat?" **(Select one response)**

Select an Answer ▼

Table 1. Incidence of outcome

Intervention Group1	N for analysis	Outcome measure	Denominator	P-value	Reference group
		☐ # of patients with one or more events	Select an Answer ▼		Select an Answer ▼
		☐ % of patients with one or more events			
		☐ # of events			
Intervention Group2	N for analysis	Outcome measure	Denominator	P-value	Reference group
		☐ # of patients with one or more events	Select an Answer ▼		Select an Answer ▼
		☐ % of patients with one or more events			
		☐ # of events			
Intervention Group3	N for analysis	Outcome measure	Denominator	P-value	Reference group
		☐ # of patients with one or more events	Select an Answer ▼		Select an Answer ▼
		☐ % of patients with one or more events			
		☐ # of events			
Intervention Group4	N for analysis	Outcome measure	Denominator	P-value	Reference group
		☐ # of patients with one or more events	Select an Answer ▼		Select an Answer ▼
		☐ % of patients with one or more events			
		☐ # of events			
Intervention Group5	N for analysis	Outcome measure	Denominator	P-value	Reference group
		☐ # of patients with one or more events	Select an Answer ▼		Select an Answer ▼
		☐ % of patients with one or more events			
		☐ # of events			
Intervention Group6	N for analysis	Outcome measure	Denominator	P-value	Reference group
		☐ # of patients with one or more events	Select an Answer ▼		Select an Answer ▼
		☐ % of patients with one or more events			
		☐ # of events			
Intervention Group7	N for analysis	Outcome measure	Denominator	P-value	Reference group
		☐ # of patients with one or more events	Select an Answer ▼		Select an Answer ▼
		☐ % of patients with one or more events			
		☐ # of events			
Intervention Group8	N for analysis	Outcome measure	Denominator	P-value	Reference group
		☐ # of patients with one or more events	Select an Answer ▼		Select an Answer ▼
		☐ % of patients with one or more events			
		☐ # of events			

Table 2. Measure of Association

Intervention	N for analysis	Point estimate (Select one response)	Measure of variability (Select one response)	95% CI	P-value	Reference group
		Select an Answer ▼	Select an Answer ▼			
Intervention Group1				☐ LL ☐ UL		Select an Answer ▼
Intervention Group2				☐ LL ☐ UL		Select an Answer ▼

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Intervention						
Intervention Group3				☐ LL ☐ UL		Select an Answer ▾
Intervention Group4				☐ LL ☐ UL		Select an Answer ▾
Intervention Group5				☐ LL ☐ UL		Select an Answer ▾
Intervention Group6				☐ LL ☐ UL		Select an Answer ▾
Intervention Group7				☐ LL ☐ UL		Select an Answer ▾
Intervention Group8				☐ LL ☐ UL		Select an Answer ▾

114. What variables, if any, were adjusted for in the model? **(Select all that apply)**

☐ Matching factors
☐ Age
☐ Sex
☐ Race/ethnicity
☐ Duration of disease
☐ Other (specify):
☐ Other (specify):
☐ Other (specify):
☐ Results not adjusted

Table 3. Mean difference from other group (G1-G2)

Intervention	N for analysis	Point estimate (Select one response) Select an Answer ▾	Measure of variability (Select one response) Select an Answer ▾	CI or IQR (Select one response) Select an Answer ▾	P-value	Reference group
Intervention Group1				☐ LL ☐ UL		Select an Answer ▾
Intervention Group2				☐ LL ☐ UL		Select an Answer ▾
Intervention Group3				☐ LL ☐ UL		Select an Answer ▾
Intervention Group4				☐ LL ☐ UL		Select an Answer ▾
Intervention Group5				☐ LL ☐ UL		Select an Answer ▾
Intervention Group6				☐ LL ☐ UL		Select an Answer ▾
Intervention Group7				☐ LL ☐ UL		Select an Answer ▾

Intervention Group8				☐ LL ☐ UL		Select an Answer ▼

Table 4. Mean difference from baseline. (This should be recorded as Final - Baseline. If the values decrease from baseline, then value should be negative. If the values increase from baseline, then the value should be positive. Note: Reference group should always be baseline.)

Intervention	N for analysis	Point estimate (Select one response) Select an Answer ▼	Measure of variability (Select one response) Select an Answer ▼	CI or IQR (Select one response) Select an Answer ▼	P-value
Intervention Group1				☐ LL ☐ UL	
Intervention Group2				☐ LL ☐ UL	
Intervention Group3				☐ LL ☐ UL	
Intervention Group4				☐ LL ☐ UL	
Intervention Group5				☐ LL ☐ UL	
Intervention Group6				☐ LL ☐ UL	
Intervention Group7				☐ LL ☐ UL	
Intervention Group8				☐ LL ☐ UL	

Table 5. Baseline measures.

Intervention	N for analysis	Point estimate (Select one response) Select an Answer ▼	Measure of variability (Select one response) Select an Answer ▼	CI or IQR (Select one response) Select an Answer ▼
Intervention Group1				☐ LL ☐ UL
Intervention Group2				☐ LL ☐ UL
Intervention Group3				☐ LL ☐ UL
Intervention Group4				☐ LL ☐ UL
Intervention Group5				☐ LL ☐ UL

Intervention Group6				☐ LL ☐ UL
Intervention Group7				☐ LL ☐ UL
Intervention Group8				☐ LL ☐ UL

Table 6. Final measures

Intervention	N for analysis	Point estimate (Select one response) Select an Answer ▼	Measure of variability (Select one response) Select an Answer ▼	CI or IQR (Select one response) Select an Answer ▼	P-value	Reference group
Intervention Group1				☐ LL ☐ UL		Select an Answer ▼
Intervention Group2				☐ LL ☐ UL		Select an Answer ▼
Intervention Group3				☐ LL ☐ UL		Select an Answer ▼
Intervention Group4				☐ LL ☐ UL		Select an Answer ▼
Intervention Group5				☐ LL ☐ UL		Select an Answer ▼
Intervention Group6				☐ LL ☐ UL		Select an Answer ▼
Intervention Group7				☐ LL ☐ UL		Select an Answer ▼
Intervention Group8				☐ LL ☐ UL		Select an Answer ▼

Comments **(Limit 250 characters)**

Comments **(Limit 250 characters)**

297. Comments **(Limit 250 characters)**

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