

Refid: 12, Skateboards: Are they really perilous? A retrospective study from a district hospital.
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Comparative Effectiveness and Safety of Pharmacologic Therapies for the Management of Crohn's Disease Study Design Form

Please complete this form for each included study.

1. Name of trial or study cohort (Select one response)

2. On what continent(s) did the study occur? (Select all that apply)

- United States
- North America (outside US)
- South America
- Europe
- Asia
- Australia
- Africa
- Other (specify):
- Not reported

3. Did the study occur at more than one study center? (Select one response)

4. Study period (Enter 4-digit year between 1900-2010)

Start year of enrollment

[Clear Response](#)

5. What study design was used? (Select one response)

If "Randomized Controlled Trial" in Q5, skip to Q8.

If a **NON-RANDOMIZED** study, what was the average follow-up period? (Enter mean or median number and then select units; if RCT, skip to next question.)

(Enter number between 0 and 100 for either mean or median)	(Select Units)
<input type="checkbox"/> Mean <input type="text"/>	<input type="text" value="Select an Answer"/>
<input type="checkbox"/> Median <input type="text"/>	
<input type="checkbox"/> Not reported	

If "Randomized Controlled Trial" in Q5, answer Q8-Q17. Otherwise, skip to Q18.

8. If a **randomized controlled trial**, select type. (Select all that apply)

- Parallel arms
- Factorial design
- Crossover design
- Other (specify):

9. If a **randomized controlled trial**, was there a period of follow-up before patients were randomized aka "run-in period"? (Select one response)

If "Yes" in Q9, answer Q10-11. Otherwise, skip to Q12.

If there was a run-in period, what was the duration of the run-in period? (Enter number and then select units)

10. (Enter number between 0 and 100)	11. (Select units)
<input type="radio"/> Duration <input type="text"/>	<input type="text" value="Select an Answer"/>

<input type="radio"/> Not reported <input type="radio"/> Clear Response	
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If a randomized controlled study, what was the duration of assigned treatment from randomization? (Enter number and then select units)

12. (Enter number between 0 and 100) <input type="radio"/> Duration <input type="text"/> <input type="radio"/> Not reported <input type="radio"/> Clear Response	13. (Select units) <input type="text" value="Select an Answer"/>
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For studies that apply to **KQ2 only**, what was the duration of response or remission prior to randomization? (Enter number and then select units)

14. (Enter number between 0 and 100) <input type="radio"/> Duration <input type="text"/> <input type="radio"/> Not reported <input type="radio"/> Clear Response	15. (Select units) <input type="text" value="Select an Answer"/>
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16. If a randomized controlled trial, was adherence reported? (Select one response)

If adherence was reported in Q16, answer Q17. Otherwise, skip to Q18.

17. If adherence was reported, was adherence $\geq 80\%$ in all study arms? (Select one response)

18. Which subgroups analyses were conducted? (Select all that apply)

- Age at diagnosis
- Age at study start
- Duration of disease
- Baseline CRP
- Baseline CDAI
- Comorbid conditions
- Gender
- Race/ethnicity
- Prior treatment
- Prior surgery
- Family history of IBD
- Smoking status
- Concurrent use of aminosalicylates
- Concurrent use of anti-TNFs
- Concurrent use of corticosteroids
- Concurrent use of thiopurines
- Concurrent use of methotrexate
- Concurrent use of other medication (specify):
- Other (specify):
- Other (specify):
- Other (specify):
- No subgroup analyses were conducted

Please select and specify the **INCLUSION** criteria. Please mark exclusion criteria as inclusion criteria (e.g., If a study excluded patients who had a previous CD surgery, then the inclusion criteria would be "No previous CD surgery.")

<input type="checkbox"/> Pediatrics <input type="checkbox"/> Adults	
<input type="checkbox"/> Crohn's disease <u>only</u> <input type="checkbox"/> IBD	
<input type="checkbox"/> Males only <input type="checkbox"/> Females only	
<input type="checkbox"/> Previous CD surgery (specify): <input type="checkbox"/> No previous CD surgery	(Specify type of surgery) <input type="text"/>
<input type="checkbox"/> CDAI score (specify criteria): <input type="checkbox"/> Pediatric CDAI score (specify criteria): <input type="checkbox"/> Harvey-Bradshaw Index (specify criteria): <input type="checkbox"/> Other index (specify name and criteria):	(If other index, specify name and criteria. If CDAI, PCDAI, or HBI, specify criteria.) <input type="checkbox"/> Other index (specify): <input type="text"/> <input type="checkbox"/> > <input type="text"/>

	<input type="checkbox"/> < <input type="text"/>
<input type="checkbox"/> Duration of remission (specify):	(Specify number of weeks, months, or years) <input type="checkbox"/> Weeks <input type="text"/> <input type="checkbox"/> Months <input type="text"/> <input type="checkbox"/> Years <input type="text"/>
<input type="checkbox"/> Previous use of medications (specify):	<input type="checkbox"/> Antibiotics <input type="checkbox"/> Aminosalicylates <input type="checkbox"/> Anti-TNFs <input type="checkbox"/> Corticosteroids <input type="checkbox"/> Thiopurines <input type="checkbox"/> Methotrexate <input type="checkbox"/> Infliximab <input type="checkbox"/> Adalimumab <input type="checkbox"/> Certolizumab pegol <input type="checkbox"/> Other (specify): <input type="text"/> <input type="checkbox"/> Other (specify): <input type="text"/> <input type="checkbox"/> Other (specify): <input type="text"/>
<input type="checkbox"/> No previous use of medications (specify):	<input type="checkbox"/> Antibiotics <input type="checkbox"/> Aminosalicylates <input type="checkbox"/> Anti-TNFs <input type="checkbox"/> Corticosteroids <input type="checkbox"/> Thiopurines <input type="checkbox"/> Methotrexate <input type="checkbox"/> Infliximab <input type="checkbox"/> Adalimumab <input type="checkbox"/> Certolizumab pegol <input type="checkbox"/> Other (specify): <input type="text"/> <input type="checkbox"/> Other (specify): <input type="text"/> <input type="checkbox"/> Other (specify): <input type="text"/>
<input type="checkbox"/> Disease activity (specify source/metric):	(Specify source/metric and then indicate disease activity) <input type="checkbox"/> Source/metric (specify): <input type="text"/> <input type="checkbox"/> Active disease <input type="checkbox"/> Inactive disease <input type="checkbox"/> Mild disease <input type="checkbox"/> Moderate disease <input type="checkbox"/> Severe disease
<input type="checkbox"/> Perianal fistulizing <input type="checkbox"/> Not pregnant <input type="checkbox"/> Not nursing <input type="checkbox"/> Using adequate contraception <input type="checkbox"/> No short bowel syndrome <input type="checkbox"/> No ostomy <input type="checkbox"/> No abscess <input type="checkbox"/> No obstructive symptoms with strictures <input type="checkbox"/> No history of tuberculosis, positive chest radiograph, or positive PPD <input type="checkbox"/> No demyelinating disease <input type="checkbox"/> No cancer	
<input type="checkbox"/> Smoking status (specify):	(Specify smoking status) <input type="text"/>
<input type="checkbox"/> Other (specify):	<input type="text"/>
<input type="checkbox"/> Other (specify):	<input type="text"/>
<input type="checkbox"/> Other (specify):	<input type="text"/>

<input type="checkbox"/> Other (specify):	<input type="text"/>
<input type="checkbox"/> Other (specify):	<input type="text"/>
<input type="checkbox"/> Other (specify):	<input type="text"/>
<input type="checkbox"/> Other (specify):	<input type="text"/>
<input type="checkbox"/> Other (specify):	<input type="text"/>
<input type="checkbox"/> Other (specify):	<input type="text"/>

55. Comments (Limit 250 characters)

56. Comments (Limit 250 characters)

57. Comments (Limit 250 characters)

and go to or Skip to Next