Devinsky 2017

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Bibliographic Reference	Devinsky, Orrin; Cross, J. Helen; Laux, Linda; Marsh, Eric; Miller, Ian; Nabbout, Rima; Scheffer, Ingrid E.; Thiele, Elizabeth A.; Wright, Stephen; Cannabidiol in Dravet Syndrome Study, Group; Trial of Cannabidiol for Drug-Resistant Seizures in the Dravet Syndrome; The New England journal of medicine; 2017; vol. 376 (no. 21); 2011-2020

Study details

Study type	Randomised controlled trial (RCT)
Study location	USA & Europe
Study setting	23 centres
Study dates	Not reported
Duration of follow-up	14 weeks
Sources of funding	GW Pharmaceuticals
Inclusion criteria	Diagnosis of Dravet syndrome Taking 1 or more antiepileptic drugs 4 or more convulsive seizures during baseline period 28 day baseline period Stable treatment including a ketogenic diet and vagus nerve stimulation, stable for 4 weeks before screening
Exclusion criteria	Not stated
Sample size	120
Outcome measures	% change in monthly seizures % change in convulsive seizure frequency Global Impression of Change

	Caregiver GIC % reduction in seizures 25%, 50%, 75%, 100% Change in seizure duration Sleep disruption Quality of life Quality of Life in Childhood Epilepsy questionnaire Hospital admissions admissions due to epilepsy Use of rescue medication

Study arms

	Cannabidiol (N = 61)
Loss to follow-up	0
% Female	43%
Mean age (SD)	9.7 (4.7)
Formulation	Cannabidiol oral solution
How dose was titrated up	14 day dose titration phase to target 20 mg/kg/day
What the maintenance dose was	20 mg/kg/day
How long the maintenance dose was sustained for	14 weeks
Monitoring/reviewing procedure	Clinical assessments at baseline and after 2, 4, 8 and 14 weeks
Stopping criteria	10 day tapering period
	Placebo (N = 59)
Loss to follow-up	1
% Female	54%

	Mean age (SD)	9.8±4.8
	Formulation	Identical placebo oral solution

- Risk of bias

Domain 1: Bias arising from the randomization process

Risk of bias judgement for this domain

Some concerns (No information for random sequence allocation or allocation concealment)

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Risk of bias for this domain

Low

Domain 3. Bias due to missing outcome data

Risk-of-bias judgement for this domain

Low

Domain 4. Bias in measurement of the outcome

Risk-of-bias judgement for this domain

Low

Domain 5. Bias in selection of the reported result

Risk-of-bias judgement domain

Low

Overall bias and Directness

Risk of bias judgement

Some concerns

(No information for random sequence allocation or allocation concealment)

Overall Directness

Partially applicable

(Patients with Dravet syndrome)