Chelwest NNU Thursday am

Journal Club

31/03/22

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Paper of the Week

Hydrocortisone to Improve Survival without Bronchopulmonary Dysplasia.

Watterberg et al, 2022.

New England Journal of Medicine.

Double-masked, placebo-controlled, randomised trial

Presented by Dr Gemma Ramsden

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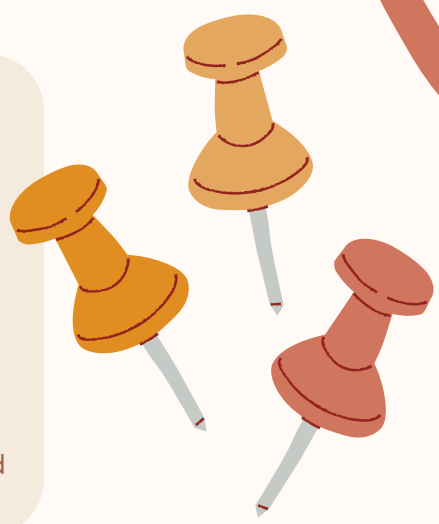
Key Question

Does low dose hydrocortisone given after 14 days of life increase survival and decrease severe bronchopulmonary dysplasia?

Recruitment:

- 12, 138 screened for eligibility
- 2301 were eligible → 35% of eligible infants had consent provided
- 800 were enrolled



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Results

There was no statistically significant difference between the two groups in survival, BPD or moderate to severe neurodevelopmental impairment

Table 2. Primary Outcomes and Their Components.*

Outcome	Hydrocortisone (N=398)	Placebo (N=402)	Rate Ratio (95% CI)†
Efficacy			
Survival without moderate or severe BPD at 36 wk of postmenstrual age — no. (%)	66 (16.6)	53 (13.2)	1.27 (0.93–1.74)
Death by 36 wk of postmenstrual age — no. (%)	19 (4.8)	28 (7.0)	0.66 (0.38–1.16)‡
Moderate or severe BPD at 36 wk of postmenstrual age — no./total no. (%)	313/379 (82.6)	321/374 (85.8)	0.96 (0.91–1.02)
Safety¶¶			
Survival without moderate or severe NDI — no./total no. (%)	132/358 (36.9)	134/359 (37.3)	0.98 (0.81–1.18)
Survival without severe NDI — no./total no. (%)	230/358 (64.2)	231/359 (64.3)	1.01 (0.90–1.12)
Known to have died by follow-up — no. (%)	43 (10.8)	46 (11.4)	0.91 (0.62–1.34)‡
Moderate or severe NDI in survivors — no./total no. (%)	183/315 (58.1)	179/313 (57.2)	1.03 (0.90–1.17)

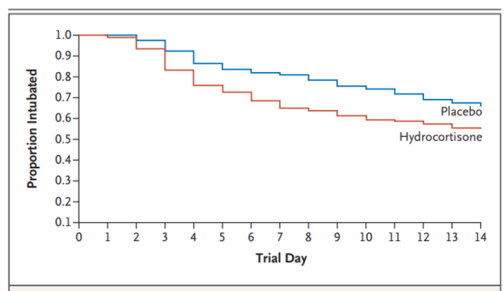

Figure 2. Infants Extubated According to Day of Treatment.
Shown are Kaplan–Meier estimates of the proportion of infants remaining intubated within the first 14 days of the trial. The probability of being extubated by the end of the treatment period was 44.7% in the hydrocortisone group and 33.6% in the placebo group. The rate ratio for extubation estimated from the proportional-hazards model was 1.54 (95% CI, 1.23 to 1.93).

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Strengths & Limitations

- Clear, focused PICO
- Methodologically sound/ blinded (except pharmacist)
- Comprehensive results
- High impact factor/ well renowned authors

- Hard to be completely sure results are applicable to local populations due to low rates of recruitment

Learning Points

Recruitment Difficulties = In the UK we have average recruitment rates of around 50% (in trials like SIFT/ Elfin).

Clinicaltrials.gov = Good place to check that trials have reported their originally specified primary & secondary outcomes (and measured them in the way that they said they would!)

Coming up!

Devon Anthony presenting on 07/04/22

Any questions/ requests please contact your friendly research fellows at katie.evans7@nhs.net or dominic.carr@nhs.net