ENDGAMES

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STATISTICAL QUESTION

Sample size: how many participants are needed in a trial?

Researchers investigated the effectiveness of a home based early intervention on children's body mass index (BMI) at age 2 years. A randomised controlled superiority trial was used. The intervention consisted of eight home visits from specially trained community nurses in the first 24 months after birth; this was in addition to the usual childhood nursing service from community health service nurses. The control group received the usual childhood nursing service alone. Participants were first time mothers and their infants. The primary outcome was children's BMI at age 2.

The sample size calculation was based on having 80% power to detect a difference in mean BMI of 0.25 units between treatment groups at age 2, using a two sided hypothesis test and critical level of significance of 0.05. It was assumed that the standard deviation of observations in each group was the same and equal to 1.5 BMI units. A total sample size of 504 participants (252 in each treatment arm) was required. To allow for an estimated 20% dropout rate it would be necessary to recruit 630 first time mothers. In total, 667 first time mothers and their infants were recruited to the trial.

At age 2 years, mean BMI was significantly lower in the intervention group compared with the control group (16.53 v 16.82; difference 0.29, 95% confidence interval −0.55 to −0.02; P=0.04). The researchers concluded that a home based early intervention delivered by trained community nurses was effective in reducing mean BMI in children at age 2 years.

Which of the following statements, if any, are true?

a) A difference in mean BMI of 0.25 between treatments was the smallest effect of clinical interest

b) If power was increased to 90%, the required sample size would increase

c) The type I error rate was fixed at 5% for the statistical test of the primary outcome

d) Increasing sample size will lead to a reduction in the type I error rate

e) It can be concluded that a difference in mean BMI of at least 0.25 between treatments definitely exists in the population

Submitted by Philip Sedgwick

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PICTURE QUIZ

An 81 year old man with a blistering rash

Rash on patient's torso

An 81 year old man presented with a 10 day history of an extensive blistering rash that was profoundly itchy. He had a history of hypothyroidism and a deep vein thrombosis. He was receiving carbimazole and warfarin and denied any recent changes in medication.

On examination he had more than 100 blisters over his whole body, although his face was spared (figure). Some of the blisters formed a circinate pattern. Nikolsky's sign was negative. The mucous membranes were not affected.

Blood tests including full blood count, urea and electrolytes, and liver function tests were within normal ranges. He had a C reactive protein of 28.8 mg/L (reference range 0-4.9; 1 mg/L=9.52 nmol/L).

1 What are the possible causes of this man's blisters?

2 Which investigations would you do to confirm your diagnosis?

3 What comorbidities are associated with this condition?

4 What is the best treatment for this condition?

Submitted by Sophie Noel, Janet Dua, and Ghazia Kaushal

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CASE REPORT

Postpartum fever and shortness of breath

A 26 year old gravida 3 para 2 woman developed fever and malaise after an uncomplicated spontaneous vaginal delivery at 38 weeks' gestation. Postpartum vaginal loss was unremarkable. Her baby, a boy with a birth weight of 3420 g, was well. Her symptoms were initially attributed to a viral illness. However, she gradually became more unwell over the next two days with lightheadedness, abdominal pain, fever, and shortness of breath, and she was noted to have tachycardia and hypotension. On the third day postpartum, while still an inpatient, she was extremely unwell. Pulse rate was 140 beats/min, blood pressure was 80/20 mm Hg, and oxygen saturations were 91% while breathing oxygen at 6 L/min. Heart sounds were dual, chest examination showed bibasal crackles, and she had hypogastric tenderness. Initial investigations were haemoglobin 96 g/L (pregnancy specific reference range 115-165), white blood cell count $11.2×10^9$/L (4-15), platelets $155×10^9$/L (150-400), prothrombin time 21 s (11-16), activated partial thromboplastin time 52.7 s (23-38), fibrinogen 13.2 µmol/L (5.1-11.8; 1µmol/L=3401 mg/dL), creatinine 136 µmol/L (1 µmol/L=0.01 mg/dL;30-70), estimated glomerular filtration rate 41 mL/min (80-120), serum bicarbonate 10 mmol/L (1 mmol/L=1 mEq/L; 22-33), and venous lactate 6.6 mmol/L (1 mmol/L=9.01 mg/dL; 0.5-2.2).

She was given intravenous antibiotics and hydrocortisone and transferred to the intensive care unit (ICU). Chest radiography showed diffuse bilateral lower zone infiltrates. A non-contrast computed tomogram of the abdomen and pelvis was unremarkable. Echocardiography showed bilateral reduction in left and right ventricular function, with a left ventricular ejection fraction (LVEF) of 40% and no evidence of endocarditis. Cardiac troponin I was raised at 0.34 µg/L (<0.05), with a subsequent peak value of 22 µg/L.

1 What is the most likely cause of the patient's initial deterioration?

2 What were the possible factors in her cardiac dysfunction?

3 What are the risks for a future pregnancy?

4 How would you manage a future pregnancy?

Submitted by Adam Morton

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