Tema 1.3.
Poblaciones y muestras

Población

- En general no podemos trabajar con toda la población
  - Individuos expuestos a HIV
  - Individuos diabéticos
  - Individuos vacunados contra la gripe
  - Fumadores
- Población diana:
  - Población a la que queremos extender las conclusiones del trabajo

Población de estudio

- En general, se estudian poblaciones que cumplan ciertos criterios de inclusión
  - La población de estudio es la que cumple estos criterios
    - Ejemplo:
      - Hombres hipertensos mayores de 45 años
      - Sin antecedentes familiares
      - Se requiere que no hayan seguido ningún tratamiento en los últimos 5 años

1: Stroke 2002 Jan;33(1):130-4

Comment in:

- Stroke. 2002 Jan;33(1):134-5.

Acetaminophen for altering body temperature in acute stroke: a randomized clinical trial.

Kasner SE, Wein T, Piriyawat P, Villar-Cordova CE, Chalela JA, Krieger DW, Morgenstern LB, Kimmel SE, Grotta JC.

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BACKGROUND AND PURPOSE: Mild alterations in temperature have prominent effects on ischemic cell injury and stroke outcome. Elevated core body temperature (CBT), even if mild, may exacerbate neuronal injury and worsen outcome, whereas hypothermia is potentially neuroprotective. The antipyretic effects of acetaminophen were hypothesized to reduce CBT. METHODS: This was a randomized, controlled clinical trial at 2 university hospitals. Patients were included if they had stroke within 24 hours of onset of symptoms, National Institutes of Health Stroke Scale (NIHSS) score > or =5, initial CBT <3 8.5 degrees C, and white blood cell count < 12 600 cells/mm(3); they were excluded if they had signs of infection, severe medical illness, or contraindication to acetaminophen. CBT was measured every 30 minutes. Patients were randomized to receive acetaminophen 650 mg or placebo every 4 hours for 24 hours. The primary outcome measure was mean CBT during the 24-hour study period; the secondary outcome measure was the change in NIHSS. RESULTS: Thirty-nine patients were randomized. Baseline CBT was the same: 36.96 degrees C for acetaminophen versus 36.95 degrees C for placebo (P=0.96). During the study period, CBT tended to be lower in the acetaminophen group (37.13 degrees C versus 37.35 degrees C), a difference of 0.22 degrees C (95% CI, -0.08 degrees C to 0.51 degrees C; P=0.14). Patients given acetaminophen tended to be more often hypothermic <36.5 degrees C (OR, 3.4; 95% CI, 0.83 to 14.2; P=0.09) and less often hyperthermic >37.5 degrees C (OR, 0.52; 95% CI, 0.19 to 1.44; P=0.22). The change in NIHSS scores from baseline to 48 hours did not differ between the groups (P=0.93). CONCLUSIONS: Early administration of acetaminophen (3900 mg/d) to afebrile patients with acute stroke may result in a small reduction in CBT. Acetaminophen may also modestly promote hypothermia <36.5 degrees C or prevent hyperthermia >37.5 degrees C. These effects are unlikely to have robust clinical impact, and alternative or additional methods are needed to achieve effective thermoregulation in stroke patients.

Muestra

- Conjunto de individuos de la población de estudio
  - La muestra se selecciona a partir de determinados criterios y en función del tipo de estudio que se va ha realizar
- Tipos básicos de muestreo
  - Aleatorio simple
  - Estratificado
  - Etapas múltiples
  - Sistemático

Muestreo aleatorio simple

- Cada individuo de la población tiene la misma probabilidad de ser seleccionado
  - Equilibrar variables no controladas
  - Evitar sesgos de selección
  - Fundamental en los ensayos clínicos

l: Anesthesiology 2002 Sep;97(3):585-91

LWWonline
Lippincott Williams & Wilkins

Clinical trial of the neuroprotectant clomethiazole in coronary artery bypass graft surgery: a randomized controlled trial.

Kong RS, Butterworth J, Aveling W, Stump DA, Harrison MJ, Hammon J, Stygall J, Rorie KD, Newman SP.

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BACKGROUND: The neuroprotective property of clomethiazole has been demonstrated in several animal models of global and focal brain ischemia. In this study the authors investigated the effect of clomethiazole on cerebral outcome in patients undergoing coronary artery bypass surgery. METHODS: Two hundred forty-five patients scheduled for coronary artery bypass surgery were recruited at two centers and prospectively randomized to clomethiazole edisilate (0.8%), 225 ml (1.8 mg) loading dose followed by a maintenance dose of 100 ml/h (0.8 mg/h) during surgery, or 0.9% NaCl (placebo) in a double-blind trial. Coronary artery grafting was completed during moderate hypothermic (28-32 degrees C) cardiopulmonary bypass. Plasma clomethiazole was measured at several intervals during and up to 24 h after the end of infusion. A battery of eight neuropsychological tests was administered preoperatively and repeated 4-7 weeks after surgery. Analysis of the change in neuropsychological test scores from baseline was used to determine the effect of treatment. RESULTS: Neuropsychological assessments were completed in 219 patients (110 clomethiazole; 109 placebo). The mean plasma concentration of clomethiazole during surgery was 66.2 microm. There was no difference between the clomethiazole and placebo group in the postoperative change in neuropsychological test scores. CONCLUSION: Clomethiazole did not improve cerebral outcome following coronary artery bypass surgery.

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Muestreo estratificado

- En primer lugar, se define un criterio que estratifica los individuos
  - P.e. niveles de colesterol como indicador de exposición a riesgo cardiovascular
- Se decide qué porcentaje de cada grupo debe aparecer en la muestra final
- Se realiza un muestreo aleatorio en cada subgrupo hasta completar la muestra necesaria

1: Anesthesiology 1992 Jul;77(1):38-46

Related Articles, NEW Links

The role of desmopressin acetate in patients undergoing coronary artery bypass surgery. A controlled clinical trial with thromboelastographic risk stratification.

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The role of desmopressin acetate in attenuating blood loss and reducing homologous blood component therapy after cardiopulmonary bypass is unclear. The purpose of this investigation was to identify a subgroup of patients that may benefit from desmopressin acetate therapy. One hundred fifteen patients completed a prospective randomized double-blind, placebo-controlled trial designed to evaluate the effect of desmopressin acetate (0.3 microgram.kg-1) on mediastinal chest tube drainage after elective coronary artery bypass grafting surgery in patients with normal and abnormal platelet-fibrinogen function as diagnosed by the maximal amplitude (MA) on thromboelastographic (TEG) evaluation. The 115 patients evaluated were divided into two groups based on the MA of the post-cardiopulmonary bypass TEG tracing. Group 1 (TEG:MA greater than 50 mm) consisted of 86 patients, of whom 44 received desmopressin and 42 received placebo. Twenty-nine patients had abnormal platelet function (TEG:MA less than 50 mm) and were designated as group 2. In group 2, 13 received desmopressin and 16 placebo. During the first 24 h after cardiopulmonary bypass, the placebo-treated patients in group 2 had significantly greater mediastinal chest tube drainage when compared to placebo patients in group 1 (1,352.6 +/- 773.1 ml vs. 865.3 +/- 384.4 ml, P = 0.002). In addition to increases in blood loss, group 2 placebo patients also were administered an increased number of blood products (P less than 0.05). The desmopressin-treated patients in group 2 neither experienced increased mediastinal chest tube drainage nor received increased amounts of homologous blood products when compared to those in group 1.(ABSTRACT TRUNCATED AT 250 WORDS)

Publication Types:

- Clinical Trial
- Randomized Controlled Trial

Muestreo en etapas múltiples (muestreo en conglomerados)

- Se definen unidades básicas que agrupan a los pacientes según ciertos criterios
  - P.e Ciudades de más de 50 habitantes
  - Hospitales de primer nivel
  - Unidades de cuidados intensivos
- Se seleccionan al azar determinadas unidades
- Se realiza una muestreo al azar dentro de las unidades seleccionadas

Muestreo sistemático

- Se sigue una determinada regla para seleccionar a los pacientes
  - P.e. Uno de cada tres
  - En una serie de pacientes, seleccionamos uno de cada cinco.
- No es muy recomendable
  - Posibles sesgos sistemáticos
    - P.e los primeros pacientes en una consulta pueden corresponder a personas de edad avanzada que suelen acudir con mucho tiempo a la consulta.

Muestras

- La muestra debe ser representativa de la población
  - Debemos evitar sesgos sistemáticos
  - Controlar variables de confusión
- El tamaño muestral juega un papel fundamental
  - La muestra debe contener suficiente información para que la inferencia que realicemos sea una generalización aceptable