SELEZIONE PUBBLICA N. 2022N37, PER TITOLI ED ESAMI, PER L'ASSUNZIONE A TEMPO INDETERMINATO DI N. 1 PERSONA DI CATEGORIA D, POSIZIONE ECONOMICA D1, AREA TECNICA, TECNICO-SCIENTIFICA ED ELABORAZIONE DATI, A TEMPO PIENO, PRESSO L'UNIVERSITÀ DEGLI STUDI DI PADOVA - TECNICO DI RICERCA "STUDY COORDINATOR" NELL'AMBITO DI TRIALS CLINICI NEL PAZIENTE CON MALATTIE DI FEGATO.

QUESITI PROVE D'ESAME

Quesiti prova scritta

1) Modelli animali di insufficienza epatica
2) Tipi di trial clinici e loro definizione
3) Basi cliniche e molecolari dell'insufficienza epatica acuta e acuta su cronica

Quesiti colloquio

Elenco n. 1:

1) Il candidato illustri come compilare un Consenso Informato;
2) Definire i punti salienti che devono essere inclusi nell'informativa del protocollo di studio e nel modulo di espressione del consenso.

Accertamento conoscenze informatiche/statistiche e della lingua inglese:

- In un foglio dati di Excel, come si traspongono i valori disposti in riga a valori disposti in colonna o viceversa?
- Traduzione del seguente brano:

  ABSTRACT:

  BACKGROUND

  Bronchiolitis, the most common infection of the lower respiratory tract in infants, is a leading cause of hospitalization in childhood. Corticosteroids are commonly used to treat bronchiolitis, but evidence of their effectiveness is limited.

  METHODS

  We conducted a double-blind, randomized trial comparing a single dose of oral dexamethasone (1 mg per kilogram of body weight) with placebo in 600 children (age range, 2 to 12 monts) with a first episode of wheezing diagnosed in the emergency department as moderate-to-severe bronchiolitis (defined by a Respiratory Distress Assessment Instrument score ≥6). We enrolled patients at 20 emergency departments during the months of November through April over a 3-year period.

  The primary outcome was hospital admission after 4 hours of emergency department observation. The secondary outcome was the Respiratory Assessment Change Score (RACS). We also evalueted later outcomes: lenght of hospital stay, later medical visits or admissions, and adverse events.

Elenco n. 2:

1) Il candidato definisca cosa sono le linee guida di Buona Pratica Clinica;
2) Quali sono le persone e gli organismi coinvolti nella Ricerca Clinica?

Accertamento conoscenze informatiche/statistiche e della lingua inglese:

- Che cos'è un ROC (Receiver Operating Characteristics) curve?

- Traduzione del seguente brano:
  ABSTRACT:
  BACKGROUND
  Bronchiolitis, the most common infection of the lower respiratory tract in infants, is a leading cause of hospitalization in coldohhod. Corticosteroids are commonly used to treat bronchiolitis, but evidence of their effectiveness is limited.
  RESULTS
  Baseline characteristics were similar in the two groups. Te admission rate was 39.7% for children assigned to dexamethasone, as compared with 41.0% for those assigned to placebo. Both groups had respiratory improvement during observation; the mean 4-hour RACS was -5.3 for dexamethasone, as compared with -4.8 for placebo. Multivariate adjustment did not significantly alter the results, nor were differences detected in later outcomes.
  CONCLUSIONS
  In infants with acute moderate-to-severe bronchiolitis who were treated in the emergency department, a single dose of 1 mg of oral dexamethasone per kilogram did not significantly alter the rate of hospital admission, the respiratory status after 4 hours of observation, or later outcomes.

Elenco n. 3:
1) Il candidato definisca la “Reazione Avversa da Farmaco” o (ADR) Adverse Drug Reaction;
2) Tipi di classificazione delle reazioni avverse da farmaco.

Accertamento conoscenze informatiche/statistiche e della lingua inglese:
- Cosa comprende o rappresenta una tabella nel programma Excel?
- Traduzione del seguente brano:
  ABSTRACT:
  BACKGROUND
  Obesity is a chronic disease with limited treatment options in pediatric patients. Liraglutide may be useful for weight management in adolescents with obesity.
  METHODS
  In this randomized, double-blind trial, which consisted of a 56-week treatment period and a 26-week follow-up period, we enrolled adolescents (12 to <18 years of age) with obesity and a poor response to lifestyle therapy alone. Participants were randomly assigned (1:1) to receive either liraglutide (3.0 mg) or placebo subcutaneously once daily, in addiction to lifestyle therapy. The primary end point was the change from baseline in the body-mass index (BMI; the weight in kilograms divided by the square of the height in meters) standard-deviation score at week 56.
  CONCLUSIONS
  In adolescents with obesity, the use of liraglutide (3.0 mg) plus lifestyle therapy led to a significantly greater reduction in BMI standard-deviation score than placebo plus lifestyle therapy.

Elenco n. 4:
1) Che cosa è un “farmaco orfano”?
2) Quali sono i criteri utilizzati per la designazione di farmaco orfano?

Accertamento conoscenze informatiche/statistiche e della lingua inglese:
- Quando si applica il Fisher exact test?
- Traduzione del seguente brano:
  RANDOMIZED TRIAL OF VACCINES FOR ZAIRE EBOLA VIRUS DISEASE - PREVAC STUDY TEAM:

Zaire Ebola virus disease (EVD) outbreaks have high mortality and morbidity, place an enormous financial and logistic burden on public health systems of affected countries, and can lead to worldwide disruption. The risk of reemergence of EVD is ever-present, as highlighted by the recurrences of EVD in the Democratic Republic of Congo and Guinea. Two vaccine strategies to prevent EVD are used: the recombinant vesicular stomatitis virus (rVSV) based vaccine expressing the surface glycoprotein of *Zaire ebolavirus* (ZEBOV) and the combination of an adenovirus type 26-vectored vaccine encoding the ZEBOV glycoprotein, followed by a booster dose of a modified vaccinia Ankara virus strain, both have received World Health Organization (WHO) prequalification status and were used during the most recent Ebola outbreaks. The ZEBOV-GP vaccine is designed as a one-dose vaccine and has been recommended for vaccination use in persons at high risk for exposure during outbreaks.

Elenco n. 5:

1) Cos'è il CRF o Case Report Form?
2) Cosa deve contenere il Case Report Form?

Accertamento conoscenze informatiche/statistiche e della lingua inglese:

- Quando evidenzi un punto o ti sposti lungo una curva ROC cosa viene mostrato nel grafico?
- Traduzione del seguente brano:

  A RANDOMIZED, CONTROLLED TRIAL OF LIRAGLUTIDE FOR ADOLESCENTS WITH OBESITY

  Obesity is a chronic and progressive disease that affects approximately 107.7 million children and adolescents worldwide and is associated with multiple coexisting conditions and complications. More than 70% of persons who have obesity before puberty will also have obesity as adults, wchich underscores the need for effective and durable interventions with adeguate safety profiles early in life. In pediatric patients, first-line treatment for obesity is tipically lifestyle therapy, which often yields poor responses. Orlistat and phentermine are the only Food and Drug Administration (FDA)-approved pharmacotherapies for the treatment of obesity in pediatric patients, and they can be used only in persons 12 years of age or older and in persons older than 16 years of age, respectively. The European Medicines Agency (EMA) has not approved any pharmacotherapeutic agents for obesity in pediatric patients. Bariatric surgery is offered to adolescents only when they have severe obesity, and it is performed infrequently. Thus, pharmacologic treatment options that can be used as adjuncts to lifestyle therapy in adolescents with obesity are of interest.

Elenco n. 6:

1) Il candidato descriva le cause dell'insufficienza epatica acuta.
2) Quali sono le manifestazioni cliniche dell'insufficienza epatica acuta?

Accertamento conoscenze informatiche/statistiche e della lingua inglese:

- Come si ordinano i dati di una colonna in Excel in ordine crescente o decrescente? E su cosa bisogna fare attenzione?
- Traduzione del seguente brano:

  EVALUATION OF SAFETY

  A noninferiority study design is increasingly being to evaluate the safety of new therapeutics. A particular challenge in noninferiority design for safety studies is that there are usually no reasonable data to justify the margin for safety. Instead, the study's clinical advisors must decide what level of adverse events is acceptable. That level might vary according to the severity of the events, the absolute risk for the patient population, and the expected benefit of the treatment in question. In the PRECISION (Prospective Randomized Evaluation of Celecoxib Integrated Safety versus Ibuprofen or Naproxen) trial, which evaluated the noninferiority of celecoxib to naproxen for the treatment of arthritis, a relative margin of 1.33 was chosen on the basis of an expected annualized risk of 2% for the primary composite end point of death

from cardiovascula causes (including hemorrhage), nonfatal myocardial infarction, or nonfatal stroke. Although this was a three-group trial, the third did not receive placebo but instead received ibuprofen, as a second noninfeiority comparator for celecoxib.

Elenco n. 7:

1) Quali sono gli aspetti principali per l'organizzazione di un laboratorio di colture cellulari?
2) Il candidato esponga le caratteristiche dei terreni di coltura cellulare che si possono utilizzare.

Accertamento conoscenze informatiche/statistiche e della lingua inglese:

- Se la distribuzione dei dati d'interesse non è normale, come devono essere descritti i dati quando cumulati: con la media ± la deviazione standard o con la mediana ± il range interquartile o dispersione?
- Traduzione del seguente brano:

  EVALUATION OF EFFICACY

  ARISTOTLE, RE-LY, and ROCKET AF Trials

  In patients with atrial fibrillation, warfarin reduces the risk of stroke, as comapred with placebo or aspirin, but is associated with an increased risk of bleeding and requires frequent blood testing to ensure a therapeutic effect. Several new oral anticoagulant agents are associated with a lower risk of bleeding and offer greater convenience, since they do not require blood testing. These agents have recently been examined and approved by the FDA on the basis of three large noninferiority trials comparing the oral anticoagulants with warfarin for the prevention of stroke or thromboembolism: ARISTOTLE (Apixaban for Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation), RE-LY (Randomized Evalutation of Long-Term Anticoagulant Therapy) and ROCKET-AF (Rivaroxaban Once Daily Oral Direct Factor Xa Inhibition Compared with Vitamin K Antagonism for Prevention of Stroke and Embolism Trial in Atrial Fibrillation):