

VUmc_CAT_TSM_B15_2018-01-08_inzage

Monday, December 18, 2017 13:02

Block 1, 50 question(s), maximum score 67
CAT TSM [08-01-2017] INZAGE**1 of 50**Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

What clinical trial is considered as pivotal trial?

- A Phase I clinical trial
- A Phase II clinical trial
- A Phase III clinical trial
- A Phase IV clinical trial

IF choice c. is selected
Set score to 1

Correct.

2 of 50Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : includeWhat aspect is not part of pharmacovigilance reporting?

- The response curve of a drug
- The overdosing of a drug
- The side-effects of a drug
- The abuse of a drug

IF choice a. is selected
Set score to 1

Correct.

3 of 50Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

You would like to include a sedated patient with sepsis in a clinical study. In this study, you aim to get a muscle biopsy from the leg to analyze the behavior of mitochondria.

How is the informed consent procedure in this situation?

- After awakening of the patient, you ask informed consent for study inclusion
- In this setting, you are not allowed to include a patient in the study
- After informed consent of two relatives you include the patient in the study
- After informed consent of one relative you include the patient in the study

IF choice d. is selected
Set score to 1

Correct.

4 of 50Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

The Medical Research Involving Human Subjects Act (WMO) forbids to perform sequential positron emission tomography tracer PK/PD studies in subjects of 30-35 years.

On which ethical principle is this based?

- Integrity
- Proportionality
- Validity
- Subsidiarity

IF choice b. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

A research protocol can be judged as non-Medical Research Involving Human Subjects Act (non-WMO) study.

When is a study approved as a non-WMO study?

- The study is performed in pediatric patients
- The study is not medical-scientific research
- The study requires only time of the patient
- The study does not subject patients to actions

IF choice b. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

An investigator would like to include a 9-year old girl with neuroblastoma in a study that aims to investigate antibody levels in young cancer patients. The burden of the study consists of a questionnaire and blood withdrawal through a venipuncture.

Is it allowed to include this patient in the study according to the Medical Research Involving Human Subjects Act (WMO)?

- Yes, after informed consent of both parents and the girl you include her in the study
- Yes, after informed consent from one parent you include her in the study
- Yes, after informed consent of both parents you include her in the study
- No, this study does not fulfill the WMO criteria for clinical research in children

IF choice d. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

What should not be included in the Discussion section of a scientific article?

- The study strengths and limitations
- The validity of the study endpoints
- A description of the research data
- The validity of the study population

IF choice c. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

You follow transgender adolescents to investigate the impact of hormones on bone growth.

What is the name for this study design?

- Cohort study
- Case-control study
- Case series
- Non-randomized controlled study

IF choice a. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

What optical technique is used to visualize structures on a nanometer level?

- Confocal scanning laser microscopy
- Electron microscopy
- Super resolution microscopy
- Fluorescence microscopy

IF choice c. is selected
Set score to 1

Correct

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

What type of carrier can be used for drug delivery to cells?

- Virus
- Liquid biopsies
- siRNA
- Bacteria

IF choice a. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

What is a publication bias?

- Non-publication of negative studies
- Over-estimating a study effect size
- Selective reporting of study outcomes
- Publication of flawed systematic reviews

IF choice a. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

You aim to perform a clinical study in patients with a disease condition that occurs only in 1:1000000 people. This study does not fit with one of the FINER criteria.

What FINER criterion is meant?

- Interesting
- Ethical
- Relevant
- Feasible

IF choice d. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

What is meant by a false discovery rate?

- The report of findings with an observer bias
- The report of false positive results
- The report of findings with a negative selection bias
- The report of false negative results

IF choice b. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

The statistical power of a study is too low. What does this mean?

- The difference in the effect observed for the control and intervention arm is too large
- The probability of falsely concluding that there was no difference between groups is high
- The deviation of the mean of a study sample is too large compared to the mean of a population
- The P-value of the study is too high to conclude that there is a difference between groups

IF choice b. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

What type of animal is not considered to be a research animal according to the Dutch Animal Law?

- A 5-day old horse fetus
- An octopus
- A butterfly larva
- A zebrafish

IF choice a. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Since the introduction of the law on animal experiments on December 18 2014, licensing of animal experiments require approval by three authorities.

What authority is not involved in the licensing of animal experiments?

- The Governmental registration and control committee (NVA)
- The Central committee for animal research (CCD)
- The Animal welfare body (IvD)
- The Ethical Animal committee (DEC)

IF choice a. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level

PorterGamGad : include

The face validity of animal models used for drug development is low. What does a low face validity mean?

- The binding profile of drugs differs between animals and humans
- The cause of disease differs between animals and humans
- The PK/PD of drugs differs between animals and humans
- The disease symptoms differ between animals and humans

IF choice d. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

You would like to register body weight changes over 2 years in high school children (age >12 years), and you write a research proposal to investigate this study objective.

You approach 100 children and their parents for a semi-structured interview of the parents. You gain body weight characteristics of the children at 2 different time points over two years.

At the end of your study you hope to be able to write a scientific publication on this topic.

Does this research proposal require ethical review by the medical research ethics committee (MREC)?

- No, because subjects are not exposed to interventions or are required to follow rules of behavior.
- Yes, you are required to approach the MREC for a non-WMO declaration.
- Yes, this is a study proposal that fulfills the criteria of the Medical Research Involving Human Subjects Act (WMO).
- No, because the study proposal does not include medical/scientific research.

IF choice b. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

In a clinical study the investigators aim to evaluate the validity of a cerebral hemoglobin oxygenation measurement device to assess brain oxygenation in clinical practice.

How is the validity of the cerebral hemoglobin oxygenation measurement device defined?

- The technical limitations of the cerebral hemoglobin oxygenation measurement device to measure brain oxygenation
- The reality that the cerebral hemoglobin oxygenation measurements indeed reflect brain oxygenation
- The predictive value of cerebral hemoglobin oxygenation measurement in the diagnosis of brain ischemia
- The degree to which repeated cerebral hemoglobin oxygenation measurements show the same results

IF choice b. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Why is independent review part of the acceptability criteria that are used by a medical ethical committee during judgment of a clinical study?

- To ensure clinical equipoise
- To ensure social accountability
- To ensure autonomy of study participants
- To ensure proportionality

IF choice b. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2

Difficulty : CTT Level
PorterGamGad : include

It is hypothesized that the combination of aspirin with the antiplatelet drug clopidogrel will reduce the risk for thrombotic events in patients with a coronary stent implant compared to patients who only receive aspirin.

How can the hypothesis be changed in such a way that the hypothesis enables a sample size calculation?

- By a better description of the drug dose
- By a better description of the drug classification
- By a better definition of the effect size
- By a better definition of the patient population

IF choice c. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

In a randomized controlled trial in two groups of 50 volunteers it was shown that vitamin D intake was associated with reduced depressive complaints by 25% compared to placebo with a P-value of 0.02.

What is the best description of this study?

- No clinical relevance without an observed effect
- Clinically relevant with an observed effect
- Clinically relevant without an observed effect
- No clinical relevance with an observed effect

IF choice b. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

How can one decrease the required sample size during a sample size calculation?

- Increase the expected variation
- Increase the expected SEM
- Increase the expected power
- Increase the expected effect size

IF choice d. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

What is a typical characteristic of an organoid?

- An organoid is an in vitro model consisting of one cell-type
- An organoid is an in vitro model with realistic micro-anatomy
- An organoid is an in vivo model with realistic micro-anatomy
- An organoid is an in vivo model consisting of one cell-type

IF choice b. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

How can a long-term toxicity study of a drug in humans be classified?

- As a Phase III study
- As a Phase I study
- As a Phase II study
- As a Phase IV study

IF choice c. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

You found that dabigatran increases the risk for bleeding during cardiac surgery. While writing the publication you doubt whether you should disclose a personal conflict of interest due to a financial relationship with the manufacturer of dabigatran.

How is this disclosure linked to the principles of the Code of Conduct for Academic Practice?
The disclosure is linked to the principle of:

- reliability
- verifiability
- scrupulousness
- independency

IF choice d. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

You design a new study that investigates the efficacy and safety of a new cardiac implant for resynchronization therapy. You decide to only include males with an incidence of cardiac arrhythmias during 4 days or more per week.

Does this decision influence the validity of your study?

- Yes, this decision reduces the external validity of the study
- No, this decision does not influence the validity of the study
- Yes, this decision reduces the reliability of the study
- Yes, this decision reduces the internal validity of the study

IF choice a. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

You suspect that chewing gum counters cognitive decline among clients with moderate to advanced dementia. You develop a study hypothesis and write a research protocol where human subjects are randomized on an institutional level. In some nursing homes, clients are allowed to chew gum on several occasions for a few minutes (intervention group). The other nursing homes provide care as usual (control group). Cognitive decline is measured by means of cognitive tests.

What type of medical/-scientific research is this?

- A non-therapeutic, interventional study with mentally incompetent subjects that requires ethical review by the Central Committee on Research Involving Human Subjects (CCMO)
- A therapeutic, interventional study with mentally incompetent subjects that requires ethical review by the medical research ethics committee'
- A non-therapeutic, interventional study that does not require ethical review by the CCMO or medical research ethics committee since chewing gum is not considered as imposed behavior
- A therapeutic, interventional study that does not require ethical review by the CCMO or medical research ethics committee since chewing gum is not considered as imposed behavior

IF choice b. is selected
Set score to 1

Correct.

29 of 50

Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Your mother is suffering from Alzheimer's disease and is graded as mentally incompetent. You would like her to participate in a novel drug trial targeting Alzheimer's disease.

How is the informed consent procedure defined in this situation?

- Informed consent is provided by relatives and the patient
- Informed consent is not required in patients with Alzheimer's disease
- This type of study cannot be performed in patients with Alzheimer's disease
- Informed consent is provided by the relatives of the patient

IF choice d. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

The overall mortality in a clinical trial in patients undergoing vascular surgery is 25%, which is higher than in the regular patient population (14%).
What is the name for this type of bias?

- Selection bias
- Publication bias
- Culture bias
- Observer bias

IF choice a. is selected
Set score to 1

Correct.

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Question 31
(2 points)

There are several experimental methods available for the inhibition of the expression of specific proteins.

Describe two different methods that can be used to suppress protein expression and explain the difference between both methods.

Anything else
Set score to 2

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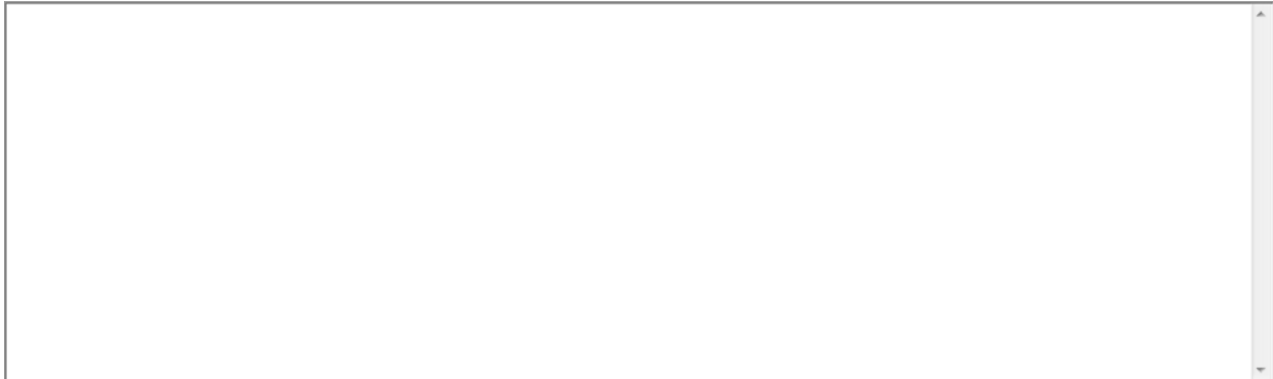
Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Question 32

(2 points)

A pharmaceutical company discovered a novel compound that targets Alzheimer's disease. Unfortunately, the scientists that have investigated the compound in experimental animals discovered that the compound cannot pass the blood-brain barrier.

Describe two methods that can be used to improve drug entry into the brain, and explain their mechanism of action.



Anything else
Set score to 2

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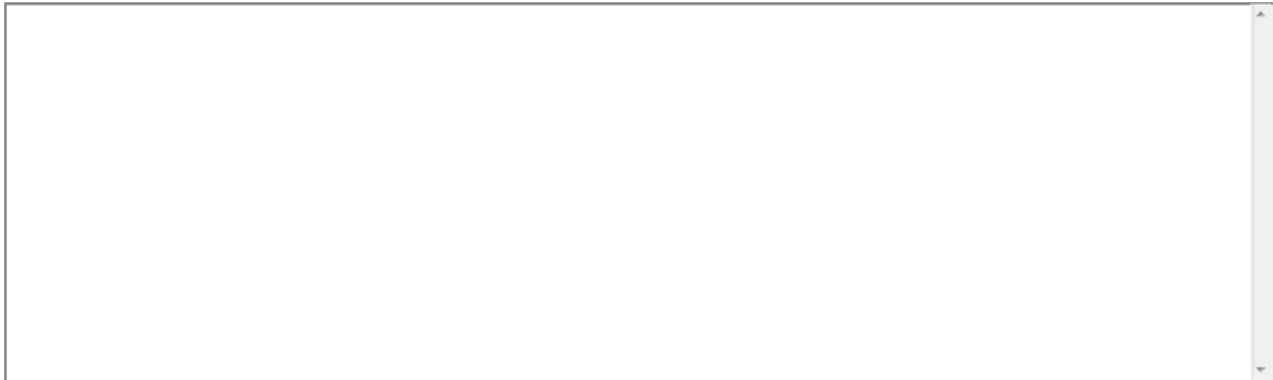
Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Question 33

(1 point)

Subsidiarity is one of the ethical principles which are considered conditional for ethical research. When subsidiarity is hampering, a protocol is considered unethical by definition.

Provide one argument in favor and one argument against this normative stance.



Anything else
Set score to 1

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Question 34

(1 point)

Why is the sample size calculation always an issue for Human Subjects Committee's (METc) while judging a clinical study protocol?
Answer the question from two different points of view: a sample size that is either too small or a sample size that is too large.



Anything else
Set score to 1

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Question 35
(3 points)

Name three examples of a selection bias in a randomized controlled trial and explain how these will influence the results of the study.

- 1.
- 2.
- 3.



Anything else
Set score to 3

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Case 1 (total of 4 points)
(question 36 and 37)

You are writing a systematic review focusing on the beneficial effects of vitamin D on inflammation in patients on the intensive care. During the literature search for the systematic review, you aim to only include randomized controlled trials.

Question 36
(2 points)

Describe a PICO for this systematic review. Be as specific as possible.

P
I
C
O



Anything else
Set score to 2

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Case 1 (total of 4 points)
(continuation)

You are writing a systematic review focusing on the beneficial effects of vitamin D on inflammation in patients on the intensive care. During the literature search for the systematic review, you aim to only include randomized controlled trials.

Question 37
(2 points)

Define a research hypothesis that fits the PICO as defined under question 36.
Make sure that the hypothesis can be used to perform a sample size calculation.



Anything else
Set score to 2

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Case 2 (total of 6 points)
(question 38 - 40)

As an investigator, you recently found that bevacizumab treatment improves overall survival in colorectal cancer. Bevacizumab acts against the vascular endothelial growth factor (VEGF). One of the proposed mechanisms of action, is that bevacizumab acts as an inhibitor of angiogenesis.

Question 38
(2 points)

Formulate a specific research question to evaluate this proposed mechanism.



Anything else
Set score to 2

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Case 2 (total of 6 points)
(continuation)

As an investigator, you recently found that bevacizumab treatment improves overall survival in colorectal cancer. Bevacizumab acts against the vascular endothelial growth factor (VEGF). One of the proposed mechanisms of action, is that bevacizumab acts as an inhibitor of angiogenesis.

Question 39
(2 points)

What would be a relevant specific clinical endpoint for this study?



Anything else
Set score to 2

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Case 2 (total of 6 points)
(continuation)

As an investigator, you recently found that bevacizumab treatment improves overall survival in colorectal cancer. Bevacizumab acts against the vascular endothelial growth factor (VEGF). One of the proposed mechanisms of action, is that bevacizumab acts as an inhibitor of angiogenesis.

Question 40
(2 points)

Propose a study design that enables you to prove a causal relationship between bevacizumab and angiogenesis following the PICO method.



Anything else
Set score to 2

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Question 41
(1 point)

Liquid biopsies may serve as a monitoring tool to detect cancer.
What is measured using this method and how does this test detect cancer?



Anything else
Set score to 1

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Question 42
(1 point)

Give two arguments why liquid biopsies are an interesting new tool to be implemented in clinical practice for the diagnosis of cancer?



Anything else
Set score to 1

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Question 43 (2 points)

The following project abstract was submitted to the committee who judges the ethics of study protocols for animal experimentation.

Background

Although hemodilution is attributed as the main cause of microcirculatory impairment during cardiopulmonary bypass (CPB), this relationship has never been investigated. We here investigated the distinct effects of hemodilution with or without CPB on microvascular perfusion and subsequent renal tissue injury in a rat model.

Methods

Male Wistar rats (375-425 g) will be anesthetized, prepared for cremaster muscle intravital microscopy, and subjected to CPB (n = 9), hemodilution alone (n = 9), or a control (sham) procedure (n = 6). Microcirculatory recordings will be performed at multiple time points and analyzed for perfusion characteristics. Kidney and lung tissue will be investigated for mRNA expression for genes regulating inflammation and endothelial adhesion molecule expression. Renal injury is assessed using immunohistochemistry.

The committee requested the investigator to apply the 3Rs to this proposal. Propose two improvements that lead to refinement, replacement or reduction.



Anything else
Set score to 2

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Case 3 (total of 6 points) (question 44 - 46)

The following rationale for a study was submitted to the MERC:

There is currently limited evidence available on the occurrence of perioperative hypovolemia in the elderly population, and whether this hypovolemic state is related to postoperative complications in these patients. More information regarding this relationship may be valuable in strategies aiming for a reduction in postoperative complications in the elderly. In particular, postoperative complications lead to long term morbidity, decreased quality of life, increased costs and are the most important factor of patient survival.

Use this rationale to design the following study items.

Question 44

(2 points)

What is a research question that fits this rationale?
Make the research question as specific as possible.

Anything else
Set score to 2

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Case 3 (total of 6 points)*(continuation)*

The following rationale for a study was submitted to the MERC:

There is currently limited evidence available on the occurrence of perioperative hypovolemia in the elderly population, and whether this hypovolemic state is related to postoperative complications in these patients. More information regarding this relationship may be valuable in strategies aiming for a reduction in postoperative complications in the elderly. In particular, postoperative complications lead to long term morbidity, decreased quality of life, increased costs and are the most important factor of patient survival.

Use this rationale to design the following study items.

Question 45

(2 points)

What is the study endpoint?
Define the study endpoint as specific as possible.

Anything else
Set score to 2

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Case 3 (total of 6 points)*(continuation)*

The following rationale for a study was submitted to the MERC:

There is currently limited evidence available on the occurrence of perioperative hypovolemia in the elderly population, and whether this hypovolemic state is related to postoperative complications in these patients. More information regarding this relationship may be valuable in strategies aiming for a reduction in postoperative complications in the elderly. In particular, postoperative complications lead to long term morbidity, decreased quality of life, increased costs and are the most important factor of patient survival.

Use this rationale to design the following study items.

Question 46

(2 points)

What patients should be selected for this study?
Define the study population as specific as possible.

Anything else

Set score to 2

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Security Briefing : Briefing

LC : y

Test name : Test 1 or 2

Difficulty : CTT Level

PorterGamGad : include

Case 4 (total of 8 points)

(question 47 - 50)

The following results are presented in an abstract of a clinical study report:

A total of 955 patients underwent randomization: 317 were assigned to the 70-mg erenumab group, 319 to the 140-mg erenumab group, and 319 to the placebo group. The mean number of migraine days per month at baseline was 8.3 in the overall population; by months 4 through 6, the number of days was reduced by 3.2 in the 70-mg erenumab group and by 3.7 in the 140-mg erenumab group, as compared with 1.8 days in the placebo group ($P < 0.001$ for each dose vs. placebo). A 50% or greater reduction in the mean number of migraine days per month was achieved for 43.3% of patients in the 70-mg erenumab group and 50.0% of patients in the 140-mg erenumab group, as compared with 26.6% in the placebo group ($P < 0.001$ for each dose vs. placebo), and the number of days of use of acute migraine-specific medication was reduced by 1.1 days in the 70-mg erenumab group and by 1.6 days in the 140-mg erenumab group, as compared with 0.2 days in the placebo group ($P < 0.001$ for each dose vs. placebo). Physical-impairment scores improved by 4.2 and 4.8 points in the 70-mg and 140-mg erenumab groups, respectively, as compared with 2.4 points in the placebo group ($P < 0.001$ for each dose vs. placebo), and everyday-activities scores improved by 5.5 and 5.9 points in the 70-mg and 140-mg erenumab groups, respectively, as compared with 3.3 points in the placebo group ($P < 0.001$ for each dose vs. placebo). The rates of adverse events were similar between erenumab and placebo. (Goadsby et al. NEJM 2017; 377:2123-2132)

Complete the abstract by designing an abstract title, and writing an introduction, methods and conclusion section.

Question 47

(2 points)

Complete the abstract by an abstract title.

Anything else

Set score to 2

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Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Case 4 (total of 8 points)
(continuation)

The following results are presented in an abstract of a clinical study report:

A total of 955 patients underwent randomization: 317 were assigned to the 70-mg erenumab group, 319 to the 140-mg erenumab group, and 319 to the placebo group. The mean number of migraine days per month at baseline was 8.3 in the overall population; by months 4 through 6, the number of days was reduced by 3.2 in the 70-mg erenumab group and by 3.7 in the 140-mg erenumab group, as compared with 1.8 days in the placebo group ($P < 0.001$ for each dose vs. placebo). A 50% or greater reduction in the mean number of migraine days per month was achieved for 43.3% of patients in the 70-mg erenumab group and 50.0% of patients in the 140-mg erenumab group, as compared with 26.6% in the placebo group ($P < 0.001$ for each dose vs. placebo), and the number of days of use of acute migraine-specific medication was reduced by 1.1 days in the 70-mg erenumab group and by 1.6 days in the 140-mg erenumab group, as compared with 0.2 days in the placebo group ($P < 0.001$ for each dose vs. placebo). Physical-impairment scores improved by 4.2 and 4.8 points in the 70-mg and 140-mg erenumab groups, respectively, as compared with 2.4 points in the placebo group ($P < 0.001$ for each dose vs. placebo), and everyday-activities scores improved by 5.5 and 5.9 points in the 70-mg and 140-mg erenumab groups, respectively, as compared with 3.3 points in the placebo group ($P < 0.001$ for each dose vs. placebo). The rates of adverse events were similar between erenumab and placebo. (Goadsby et al. NEJM 2017; 377:2123-2132)

Complete the abstract by designing an abstract title, and writing an introduction, methods and conclusion section.

Question 48
(2 points)

Write an introduction section with a maximum of 75 words for this abstract.

Anything else
Set score to 2

49 of 50

Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Case 4 (total of 8 points)
(continuation)


The following results are presented in an abstract of a clinical study report:

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Complete the abstract by designing an abstract title, and writing an introduction, methods and conclusion section.

Question 49
(2 points)

Write a methods section with a maximum of 75 words for this abstract.



Anything else
Set score to 2

50 of 50

Security Briefing : Briefing
LC : y
Test name : Test 1 or 2
Difficulty : CTT Level
PorterGamGad : include

Case 4 (total of 8 points)
(continuation)

The following results are presented in an abstract of a clinical study report:

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Complete the abstract by designing an abstract title, and writing an introduction, methods and conclusion section.

Question 50
(2 points)

Write a conclusion section with a maximum of 75 words for this abstract.



Anything else
Set score to 2

Feedback
0% to 100%

%SESSION.SCORE% of %SESSION.MAX% of the closed questions are correctly answered.
The open questions have not yet been assessed.

