



UČNI NAČRT PREDMETA / COURSE SYLLABUS

Ime predmeta:	Metode raziskovalnega dela v medicini z medicinsko statistiko
Course title:	Methods of research work in medicine with medical statistics

Študijski program in stopnja Study programme and cycle	Študijska smer Study option	Letnik Year of study	Semester Semester
Splošna medicina, enovit magistrski študijski program		Prvi	2.
General medicine, Uniform master's degree study program		First	2nd

**Vrsta predmeta (obvezni ali izbirni) /
Course type (compulsory or elective)**

obvezni

compulsory

Univerzitetna koda predmeta / University course code:

Predavanja Lectures	Seminar Seminar	Vaje Tutorial			Klinične vaje Clinical training	Druge oblike študija Other forms of study	Samost. delo Individual work	ECTS
20	10	30					60	4
		SV	LV	RV				
		10	20					

**Nosilec predmeta / Course
coordinator:**

red. prof. dr. Pavel Skok

Jeziki /Languages:

Predavanja / Lectures: slovenski/slovene

Vaje / Tutorial: slovenski/slovene

Pogoji za vključitev v delo oz. za opravljanje študijskih obveznosti:

Pogojev ni.

Prerequisites for enrolling in the course or for performing study obligations:

None.

Vsebina (kratek pregled učnega načrta):

Opredelevitev pojma znanosti. Razmejitev med strokovnim in raziskovalnim delom kot virom novega znanja. Spoznati splošne metode znanstveno raziskovalnega dela, pomen povezanosti teoretičnih znanj in uporabe v klinični medicini, algoritmi odločanja. Raziskovalno delo kot metoda preverjanja kliničnih odločitev in odgovornega sledenja posledic. Eticna in pravna vprašanja pri raziskovanju v biomedicini, odnos med zdravnikom, farmacevtsko industrijo in bolnikom, njegova obveščenost in soodločanje. Definiranje odnosov vzrok – posledica v biomedicini in vloga presejalnih testov.

Content (syllabus outline):

Definition of the term science. Boundaries between scientific and research work as sources of new knowledge. Common methods of scientific research, meaning of liaison of theoretical knowledge and its application in clinical medicine, algorithms of decision making. Research work as method of clinical decisions and responsible consequences following-up testing. Ethical and legislative questions in biomedicine research, relationship between physician, pharmaceutical industry and patient's acknowledgment and decision-making. Definition of relationship cause – consequence in biomedicine and role of screening tests.

Razumevanje osnovnih statističnih pojmov v biomedicini (incidenca, prevalenca, pozitivna in negativna napovedna vrednost, občutljivost in specifičnost testov, lažno pozitivnih in negativnih rezultatov), pomena relativnega tveganja in razmerja obetov. Razlikovanje prospektivnih, retrospektivnih, epidemioloških, kontroliranih, randomiziranih, kohortnih, primer – kontrola in dvojno slepih vrst raziskav. Pomen računalniške tehnologije in statističnih orodij pri znanstvenem raziskovalnem delu. Statistični del: raziskovalni proces, kvalitativna in kvantitativna analiza podatkov osnovni statistični pojmi (vrste spremenljivk, verjetnostne porazdelitve, mere centralne tendence in mere variabilnosti), osnove statističnega sklepanja (frekvenčna porazdelitev, ničelna domneva, standardna napaka, interval zaupanja), univariatna statistična analiza (predstavitev podatkov: tabelarna, grafična), univariatni statistični testi, bivariatna statistična analiza (odvisnosti med spremenljivkama), bivariatni parametrični testi (t-test, korelacija, ANOVA, t- test za odvisne vzorce), bivariatni neparametrični statistični testi (Mann-Whitney U test, neparametrična korelacija, hi-kvadrat test, Kruskal-Wallis H test, Median test, neparametrični statistični testi za odvisne vzorce).

Osnove genetike, anatomije in fiziologije laboratorijskih živali.

Primerjava laboratorijskih živali in človeka, prednosti in slabosti živalskih modelov.

Etika pri delu z laboratorijskimi živalmi.

Osnove zakonodaje na področju laboratorijskega dela in dela z laboratorijskimi živalmi.

Celični in tkivni modeli v predkliničnem raziskovanju.

Gensko spremenjeni organizmi in njihova vloga v predkliničnih raziskavah.

Elektro- in opto-fiziološke metode.

Obdelava in statistična analiza podatkov pri predkliničnem raziskovanju.

Pregled literature in dostop do znanstvene literature.

Publiciranje v predkliniki.

Kako povezati klinične študije in laboratorijske raziskave: temeljni principi znanstvene metodologije, orodja za pregled in analizo znanstvene literature, oblikovanje hipoteze in načrtovanje študije; objava izsledkov v obliki znanstvenih člankov

Integrirani sistemi za dostop do podatkovnih zbirk na področju biomedicine: Entrez (NCBI)-PubMed, OMIM, Gene, Protein, Enseble..

Comprehension of basic statistic terms in biomedicine (incidence, prevalence, positive and negative prognostic values, sensitivity and specificity of tests, false positive and negative results), meaning of relative risk and expectation ratio. Distinguishes between prospective, retrospective, epidemiologic, followed-up, randomised, cohort , case – control, and double blind researches. Importance of computer technology and statistic software in scientific research work. Statistical part: the research process, qualitative and quantitative data analysis, basic statistical concepts (types of variables, probability distributions, central tendency and measures of variability), basics of statistical conclusions (frequency distribution, null hypothesis, standard error, confidence interval), univariate statistical analysis (presentation of data: tables, graphs), single variant statistical tests, bivariate statistical analysis (dependence between variables), bivariate parametric tests (t - test, correlation, ANOVA, t-test for paired samples), bivariate nonparametric statistical tests (Mann - Whitney U test, non-parametric correlation, chi-square test, Kruskal - Wallis H test and the median test, nonparametric statistical tests for dependent samples).

Basic genetics, anatomy and physiology of laboratory animals.

Comparison between laboratory animals and humans, advantages and disadvantages of animal models.

Animal research ethics.

Legislation in the field of laboratory work and work with laboratory animals.

Cellular and tissue models in basic medical research

Genetically modified organisms and their role in basic medical research.

Electrical and optical methods in basic medical research

Statistical analysis of data in basic medical research.

Literature review and access to scientific literature.

Publishing in basic medical research.

How to combine clinical studies with laboratory research: basic principals of scientific methodology, tools for literature analysis, development of hypothesis, experimental study design, publication of scientific papers and doctoral thesis;

different approaches for integration of laboratory analysis (biochemical, genetic) into clinical studies

Različni pristopi uporabe laboratorijskih preiskav (biokemijskih in genetskih) kot dopolnitev in nadgradnja kliničnih študij

Pregled najnovejših laboratorijskih tehnologij uporabnih za klinične študije;

Seminarske vaje:

Metode statistične genetike za iskanje povezav genotip/fenotip

Laboratorijske vaje:

Analiza krvi in urina: hematološke, biokemijske in imunološke preiskave;

Pretočna citometrija;

Proteomske analize – Uporaba 1D/2D SDS-PAGE, Western blot, LC-MS

Genetske in epigenetske analize: genska tipizacija polimorfizmov SNP, genska ekspresija sekvenciranje naslednje generacije.

Integrated systems for biomedical data retrieving: ENTREZ (NCBI)-PubMed, OMIM, Gene, Protein, Ensemble...

Overview of the state-of art laboratory technologies most relevant for intergration into clinical studies;

Seminars:

Statistical genetic methods for identification of genotype/phenotype corellations

Laboratory:

Blood and urine analysis: heamotlogical, biochemical and immunological parameters;

Flow cytometry

Proteomics: 1d/2D SDS-PAGE, Western blot, LC-MS

Genetic analysis: genotyping of SNPs, gene expression, next generation sequencing

Temeljni literatura in viri / Reading materials:

1. Denzin N. K., Yvonna S. Lincoln Y. S. (ed.) The SAGE handbook of qualitative research / 5th ed. - Thousand Oaks [etc.] : SAGE, cop. 2018.

Dopolnilna literatura in viri

1. Hau J. and Van Hoosier G. L.: Handbook of laboratory animal science. Third edition, Volume I, II and III. CRC Press, 2010-2013.
2. Fox. J.G.: The mouse in biomedical research. Second edition. Volume I & II. Academic Press, 2006.
3. Molleham A. Patch Clamping An Introductory Guide to Patch Clamp Electrophysiology. Wiley & Sons, 2003.
4. Pawley J. Handbook of Biological Confocal Microscopy. Third edition. Springer, 2006.
5. Zakon o zaščiti živali (uradno prečiščeno besedilo) (ZZZiv-UPB3), Uradni list RS, št. 38/2013 z dne 3. 5. 2013.
6. Pravilnik o pogojih za izvajanje poskusov na živalih. Uradni list RS, št 37/2013, 29. 4. 2013.
7. Field A. Discovering statistics using SPSS. 3rd ed. SAGE Publications, 2009.
8. Robert Nussbaum, Roderick McInnes, Huntington Willard. Thompson & Thompson Genetics in Medicine. 8th ed., Philadelphia : Elsevier, 2015

Cilji in kompetence:

Poglavitni cilj predmeta je pridobitev nekaterih teoretičnih znanj in praktičnih veščin, ki jih potrebuje raziskovalec pri raziskovalnem delu v biomedicini.

Razumeti pomen znanosti in pogojev za raziskovalno delo ter ustvarjanje novega znanja. Ustvariti razmišljajoc odnos do raziskav v biomedicini, molekularni biologiji, genski tehnologiji, fiziologiji, anatomiji. Spoznati osnove raziskovalnega dela v biomedicini in bioznanostih, povezavo in pomen epidemiologije, biostatistike in njenih orodij (statisticnih testov, vrednotenja), vloga izsledkov na odločanje.

Študenti bodo znali na osnovi pregleda znanstvene literature ugotoviti trenutno stanje znanja na področju

Objectives and competences:

The major aim of the course is to gain the theoretical knowledge and practical skills needed for a researcher in biomedical research. Understanding the meaning of science and research work conditions and new knowledge acquiring. Establishment of contemplative approach to researches in biomedicine, molecular biology, genetictchnology, physiology, anatomy. Acquiring of basic knowledge about researching in biomedicine and biosciences, relationship and importance of epidemiology, biostatistics and their tools (statistic tests, evaluation) importance of findings for decision making.

Students will be able to perform systematic review of scientific literature and to establish the state-of-art in the specific biomedical research topic. Students will be able to identify relevant open scientific questions, to set the

določene biomedicinske problematike, odkriti še neodgovorjena relevantna znanstvena vprašanja, postaviti hipotezo in načrtovati biomedicinsko študijo, ki bo ustrezno ovrednotila hipotezo. Študenti bodo sposobni napisati in izvesti raziskovalni projekt s katerim bodo odgovorili na določena klinična vprašanja s pomočjo rezultatov biokemijskih in genetskih laboratorijskih preiskav.

Študenti bodo poznali in razumeli delovanje najpomembnejših tehnologij za raziskovanje na področju biomedicine, predvsem biokemije in genetike, in bodo znali uporabiti tehnologije za reševanje relevantnih kliničnih vprašanja.

appropriate hypothesis and to design biomedical study to evaluate the hypothesis. Students will be able to write and execute the research project to answer specific clinical questions using the results from biochemical and genetic laboratory investigations.

Students will understand the working the state-of-art laboratory technology most relevant for biomedical research, including biochemistry and genetics, and will be able to use the technology to adress relevant clinical issues.

Predvideni študijski rezultati:

Znanje in razumevanje: pomena znanosti, kritičnega vrednotenje izsledkov raziskav v biomedicini in preverjanje domnev. Zavedanje možnih napak pri analizah, sklepanju in prikazovanju rezultatov. Sposobnost analize znanstveno raziskovalnih prispevkov, vsebinska in kvalitativna.

Prenesljive/ključne spretnosti in drugi atributi: Načrtovanje raziskave, pomen natančnosti in točnosti pri zbiranju podatkov in izvajanju raziskave, obdelava in kvantitativna/kvalitativna interpretacija pridobljenih rezultatov v skladu z znanimi dejstvi in pridobljenimi novimi spoznanji.

Intended learning outcomes:

Knowledge and understanding: knowledge and understanding of science, critical assessment of the research results in biomedicine and hypothesis testing. Awareness of possibility of false analyse results, conclusions and result presentation. Ability of scientific research contributions, content and quality analyse.

Transferable/Key Skills and other attributes: research planning, meaning of precision and accuracy in data collection, carrying out of the research, data processing, quantitative and qualitative interpretation of results according to known facts and new findings.

Metode poučevanja in učenja:

interaktivna predavanja
E-učenje
problem-based seminars
praktične vaje

Learning and teaching methods:

Interactive lectures
E-learning
problem-based seminars
practicals

Načini ocenjevanja:

Način (pisni izpit, ustno izpraševanje, naloge, projekt)
ŠTUDIJSKE OBVEZNOSTI ŠTUDENTOV
Glede na sklep Senata z dne 13. 6. 2011 je za študente obvezna 50 % udeležba na predavanjih.
POGOJI ZA PRISTOP K POSAMEZNEMU PREVERJANJU ZNANJA: opravljen seminar in vaje.
Računalniški izpit

Delež (v %) /
Share (in %)

100

Assessment methods:

Type (examination, oral, coursework, project):
ACADEMIC OBLIGATIONS OF STUDENTS
According to the decision of the Senate on June 13, 2011, 50% attendance at lectures is obligatory for students.
REQUIREMENTS FOR ACCESS TO INDIVIDUAL KNOWLEDGE CHECKING: completed seminar assignment and exercises
Computer exam

Reference nosilca / Course coordinator's references:

1. MAHNIČ, Aleksander, PINTAR, Špela, **SKOK, Pavel**, RUPNIK, Maja. Gut community alterations associated with *Clostridioides difficile* colonization in hospitalized gastroenterological patients with or without inflammatory bowel disease. *Frontiers in microbiology*. Sep. 2022, vol. 13, str. 1-8, ilustr. ISSN 1664-302X. <https://doi.org/10.3389/fmicb.2022.988426>, DOI: [10.3389/fmicb.2022.988426](https://doi.org/10.3389/fmicb.2022.988426). [COBISS.SI-ID [120477443](https://doi.org/10.3389/fmicb.2022.988426)], [JCR, SNIP, WoS do 14. 4. 2023:
2. GORENJAK, Mario, JEZERNIK, Gregor, KRUŠIČ, Martina, **SKOK, Pavel**, POTOČNIK, Uroš. Identification of novel loci involved in adalimumab response in Crohn's disease patients using integration of genome profiling and isoform-level immune-cell deconvoluted transcriptome profiling of colon tissue. *Pharmaceutics*. [Online ed.]. Sep. 2022, vol. 14, issue 9, str. 1-16, ilustr. ISSN 1999-4923. <https://doi.org/10.3390/pharmaceutics14091893>, <https://www.mdpi.com/1999-4923/14/9/1893>, DOI: [10.3390/pharmaceutics14091893](https://doi.org/10.3390/pharmaceutics14091893). [COBISS.SI-ID [120609795](https://doi.org/10.3390/pharmaceutics14091893)], [JCR, SNIP, WoS do 18. 8. 2023:
3. FIJAČKO, Nino, MASTERSON CREBER, Ruth, GOSAK, Lucija, ŠTIGLIC, Gregor, EGAN, Dominic, CHAKA, Brian, DEBELJAK, Nika, STRNAD, Matej, **SKOK, Pavel**. Evaluating quality, usability, evidence-based content, and gamification features in mobile learning apps designed to teach children basic life support: systematic search in apps stores and content analysis. *JMIR mhealth and uhealth*. 2021, vol. 9, issue 7, str. 1-16, ilustr. ISSN 2291-5222. <https://mhealth.jmir.org/2021/7/e25437>, DOI: [10.2196/25437](https://doi.org/10.2196/25437). [COBISS.SI-ID [72125699](https://doi.org/10.2196/25437)], [JCR, SNIP, WoS do 2. 3. 2024:
4. GORENJAK, Mario, ZUPIN, Mateja, JEZERNIK, Gregor, SKOK, Pavel, POTOČNIK, Uroš. Omics data integration identifies ELOVL7 and MMD gene regions as novel loci for adalimumab response in patients with Crohn's disease. *Scientific reports*. 2021, vol. 11, str. 1-12, ilustr. ISSN 2045-2322. <https://www.nature.com/articles/s41598-021-84909-z>, <https://doi.org/10.1038/s41598-021-84909-z>, DOI: [10.1038/s41598-021-84909-z](https://doi.org/10.1038/s41598-021-84909-z). [COBISS.SI-ID [54882051](https://doi.org/10.1038/s41598-021-84909-z)], [JCR, SNIP, WoS do 7. 11. 2023:
5. ČERANIĆ, Davorin, ZORMAN, Milan, **SKOK, Pavel**. Interleukins and inflammatory markers are useful in predicting the severity of acute pancreatitis. *Bosnian journal of basic medical sciences*. 2020, vol. 20, no. 1, str. 99-105, ilustr. ISSN 1840-4812. <https://www.bjbms.org/ojs/index.php/bjbms/article/view/4253/1234>, <http://dx.doi.org/10.17305/bjbms.2019.4253>, DOI: [10.17305/bjbms.2019.4253](https://doi.org/10.17305/bjbms.2019.4253). [COBISS.SI-ID [6734655](https://doi.org/10.17305/bjbms.2019.4253)], [JCR, SNIP, WoS do 1. 3. 2024: št. citatov (TC): 14, čistih citatov (CI): 14, DOI: [10.14528/snr.2020.54.2.2991](https://doi.org/10.14528/snr.2020.54.2.2991). [COBISS.SI-ID [20636931](https://doi.org/10.14528/snr.2020.54.2.2991)]
6. **SKOK, Pavel**, SKOK, Kristijan. Urgent endoscopy in patients with "true foreign bodies" in the upper gastrointestinal tract : a retrospective study of the period 1994-2018 = Notfallendoskopie bei Patienten mit Fremdkörpern im oberen Gastrointestinaltrakt : eine retrospektive Studie von 1994 bis 2018. *Zeitschrift für Gastroenterologie*. Mär. 2020, jg. 58, nr. 3, str. 217-223, ilustr. ISSN 0044-2771. <https://www.thieme-connect.com/products/ejournals/abstract/10.1055/a-1062-9011>, DOI: [10.1055/a-1062-9011](https://doi.org/10.1055/a-1062-9011).

1.02 Pregledni znanstveni članek

7. **SKOK, Pavel**, SKOK, Kristijan. Gut microbiota and the pathophysiology of cardiovascular disease. *Archives of Medical Science*. 2021, [v tisku][str. 1-24], ilustr. ISSN 1896-9151. <https://www.archivesofmedicalscience.com/Gut-microbiota-and-the-pathophysiology-of-cardiovascular-disease,127177,0,2.html>, DOI: [10.5114/aoms/127177](https://doi.org/10.5114/aoms/127177). [COBISS.SI-ID [57512195](https://doi.org/10.5114/aoms/127177)], [JCR, SNIP]

1. .