2017/2018

Univerza v Mariboru

Medicinska fakulteta

UČNI NAČRT PREDMETA / COURSE SYLLABUS	
Predmet:	**Klinična farmakokinetika**
Course title:	**Clinical Pharmacokinetics**

Študijski program in stopnja Study programme and level	Študijska smer Study field	Letnik Academic year	Semester Semester
BIOMEDICINSKA TEHNOLOGIJA BIOMEDICAL TECHNOLOGY		**2**	**3 ali 4**

Vrsta predmeta / Course type

Univerzitetna koda predmeta / University course code:

Predavanja Lectures	Seminar Seminar	Sem. vaje Tutorial	Lab. vaje Laboratory work	Teren. vaje Field work	Samost. delo Individ. work	ECTS
15	**30**	**-**	**-**	**-**	**105**	**5**

Nosilec predmeta / Lecturer:	**doc. dr. Uroš Maver**
Sonosilci predmeta / Lecturer	**izr. prof. dr. Sebastjan Bevc in doc. dr. Matej Breznik**

Jeziki / Languages:	**Predavanja / Lectures:**	Slovenščina/Slovene
	Vaje / Tutorial:	Slovenščina/Slovene

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

Kandidat mora doseči 300 ECTS na predhodnem študiju.

Prerequisits:

Graduate degree 300 ECTS

Vsebina:

- zdravilna učinkovina, formulacije in dostavni sistemi (zdravila), farmakokinetika (LADME), farmakodinamika, terapevtski učinki zdravil
- sistemska in lokalna dostava zdravilnih učinkovin
- modeli vrednotenja biološke uporabnosti in bioekvivalence zdravil
- prostorski in fiziološki modeli vrednotenja farmakokinetike in farmakodinamike
- vplivi na variabilnost kliničnih učinkov zdravil in njihovo individualno odmerjanje
- odmerjanje zdravil glede na starost, težo, bolezensko stanje, hkratno uživanje hrane in druge posebne lastnosti bolnika
- vpliv genetskega polimorfizma na odmerjanje zdravil (farmakokinetični in farmakodinamski vidiki)
- mehanizmi sočinkovanja med zdravili
- individualna in populacijska farmakokinetika.

Content (Syllabus outline):

- drug, drug formulation and delivery systems (medicines), pharmacokinetics (LADME), pharmacodynamics, the therapeutic drug effects
- systemic and local delivery of drugs
- models for bioavailability and bioequivalence evaluation
- spatial and physiological pharmacokinetic and pharmacodynamic models
- variation in clinical drug effects and the according drug dosage adjustment
- drug dosing based on age, weight, medical condition, concomitant food intake and other specific patient characteristics
- the influence of genetic polymorphisms on drug dosing (pharmacokinetic and pharmacodynamic aspects)
- mechanisms of drug interactions
- individual and population pharmacokinetics

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Temeljni literatura in viri / Readings:

- M. Rowland, T. N. Tozer, Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications, Fourth Edition, Lippincot Williams & Wilkins, Philadelphia, 2010.
- L. A. Bauer, Applied Clinical Pharmacokinetics, 3rd edition, McGraw-Hill, New York, 2014.
- l. Shargel, A. H. Mutnick, P. F. Souney, L. N. Swanson, Comprihensive Pharmacy Review, Lippincot Williams & Wilkins, Philadelphia, Seventh edition, 2009.
- l. Shargel, A. H. Mutnick, P. F. Souney, L. N. Swanson, Comprehensive Pharmacy Review, Practice Exams, Lippincot Williams & Wilkins, Philadelphia, Seventh edition, 2008.
- Tekoča periodika: Clinical Pharmacokinetics (https://link.springer.com/journal/40262)

Cilji in kompetence:

- Vplivi procesov sproščanja, absorpcije, distribucije, metabolizma in eliminacije učinkovin na učinkovitost in varnost zdravil v različnih fizioloških in patoloških stanjih
- Na osnovi spremljanja koncentracij učinkovin v plazmi zagotavljati optimizacijo načrtovanja režimov odmerjanja zdravil (izbor farmacevtske oblike/ načina dajanja, odmerka, intervala odmerjanja)

Objectives and competences:

- Influence of release, absorption, distribution, metabolism and elimination of drugs on their efficacy and safety in different physiologic and pathologic conditions
- On the basis of therapeutic drug monitoring, optimizing drug dosage regimen design (selection of drug formulation/mode of administration, dose and dosage interval)

Predvideni študijski rezultati:

Znanje in razumevanje:

- Študent osvoji znanje in razumevanje za napovedovanje in interpretacijo kliničnih učinkov zdravil v realnih kliničnih situacijah.

Študent dobi poglobljeno razumevanje glede odmerjanja zdravil v povezavi s klinično farmakokinetiko.

Intended learning outcomes:

Knowledge and understanding:

- Student gains knowledge and understanding for prediction and interpretation of drug responses in real clinical settings

Student gains comprehensive knowledge about drug dosing in relation to clinical pharmacokinetics aspects.

Metode poučevanja in učenja:

Predavanja
Seminarji
Samostojno delo

Learning and teaching methods:

Lectures
Tutorials
Individual work

Načini ocenjevanja:	Delež (v %) / Weight (in %)	**Assessment:**
pisni izpit,	**60%**	written examination,
seminarska naloga (pisna in predstavitev)	**40%**	seminars (written and presented)

Reference nosilca / Lecturer's references:

1. SABOTI, Denis, **MAVER, Uroš**, CHAN, Hak-Kim, PLANINŠEK, Odon. Novel budesonide particles for dry powder inhalation (DPI) prepared using a microfluidic reactor coupled with ultrasonic spray freeze drying. Journal of pharmaceutical sciences, ISSN 1520-6017, str. 1-8.
2. MAVER, Tina, KUREČIČ, Manja, SMRKE, Dragica, STANA-KLEINSCHEK, Karin, **MAVER, Uroš**. Electrospun nanofibrous CMC/PEO as a part of an effective pain relieving wound dressing. Journal of sol-gel science and technology, ISSN 0928-0707, September 2016, vol. 79, iss. 3, str. 475-486.
3. FINŠGAR, Matjaž, PERVA-UZUNALIĆ, Amra, STERGAR, Janja, GRADIŠNIK, Lidija, **MAVER, Uroš**. Novel chitosan/diclofenac coatings on medical grade stainless steel for hip replacement applications. Scientific reports, ISSN 2045-2322, Published online:24 May 2016, vol. 6, art. no. 26653, str. 1-17.
4. MAVER, Tina, **MAVER, Uroš**, MOSTEGEL, Florian, GRIEßER, Thomas, SPIRK, Stefan, SMRKE, Dragica, STANA-KLEINSCHEK, Karin. Cellulose based thin films as a platform for drug release studies to mimick wound dressing materials. Cellulose, ISSN 0969-0239, Feb. 2015, vol. 22, iss. 1, str. 749-761.
5. NADRAH, Peter, **MAVER, Uroš**, JEMEC, Anita, TIŠLER, Tatjana, BELE, Marjan, DRAŽIĆ, Goran, BENČINA, Mojca, PINTAR, Albin, PLANINŠEK, Odon, GABERŠČEK, Miran. Hindered disulfide bonds to regulate release rate of model drug from mesoporous silica. ACS applied materials & interfaces, ISSN 1944-8244. [Print ed.], 2013, vol. 5, issue 9, str. 3908-3915.
6. HOJS, Nina, **BEVC, Sebastjan**, PEČOVNIK-BALON, Breda, HOJS, Radovan, EKART, Robert. Paricalcitol reduces proteinuria in non-dialysis chronic kidney disease patients. *Therap. apher. dial.* 2013 (Online), str. 368-372.
7. BAKRIS, George L., PITT, Bertram, WEIR, Matthew R., FREEMAN, Mason W., MAYO, Martha R., GARZA, Dahlia, STASIV, Yuri, ZAWADZKI, Rezi, BERMAN, Lance, BUSHINSKY, David A., **BEVC, Sebastjan** (sodelavec pri raziskavi),

ŽURAN, Ivan (sodelavec pri raziskavi), VUJKOVAC, Bojan (sodelavec pri raziskavi), LAINŠČAK, Mitja (sodelavec pri raziskavi), KLANČIČ, Dimitrij (sodelavec pri raziskavi), RUS, Igor (sodelavec pri raziskavi), et al. Effect of patiromer on serum potassium level in patients with hyperkalemia and diabetic kidney disease: the AMETHYST-DN randomized clinical trial. JAMA, 2015, vol. 314, no. 2, str. 151-161, ilustr.

8. **BEVC, Sebastjan**. Aldosteron, zaviralci aldosteronskih receptorjev in kronična ledvična bolezen = Aldosterone, aldosterone receptor blockers and chronic kidney disease. *Zdrav Vestn (Tisk. izd.)*. [Tiskana izd.], nov. 2011, letn. 80, št. 11, str. 838-844.
9. **BEVC, Sebastjan**, EKART, Robert, HOJS, Radovan. Serum creatinine and estimation of kidney function. V: PERKINS, Ivan H. (ur.), CHAPMAN, Catherine M. (ur.). *Creatinine : production, diagnostic uses and role in renal disease*, (Biochemistry research trends). New York: Nova Science, cop. 2012, str. [151]-160.
10. EKART, Robert, **BEVC, Sebastjan**, HOJS, Radovan, HOJS, Nina. Proteinuria and albuminuria during and after paricalcitol treatment in chronic kidney disease patients. *The journal of clinical pharmacology*, 2015 (Online), str. 1-8, ilustr.
11. PLANINŠEK, Odon, PLANINŠEK, Daniela, ZEGA, Anamarija, **BREZNIK, Matej**, SRČIČ, Stanko. Surface analysis of powder binary mixtures with ATR FTIR spectroscopy. *International journal of pharmaceutics*, ISSN 0378-5173. [Print ed.], 2006, vol. 319, no. 1-2, str. 13-19.
12. ŠTEFANIČ, Petra, SIMONČIČ, Zvone, **BREZNIK, Matej**, PLAVEC, Janez, ANDERLUH, Marko, ADDICKS, Elisabeth, GIANNIS, Athanassios, KIKELJ, Danijel. Conformationally tailored N-[(2-methyl-3-oxo-3,4-dihydro-2H-1,4-benzoxazin-2-yl)carbonyl]proline templates as molecular tools for the design of peptidomimetics. Design and synthesis of fibrinogen receptor antagonists. *Organic and Biomolecular Chemistry*, ISSN 1477-0520. [Print ed.], 2004, vol. 2, no. 10, str. 1511-1517.
13. AVSEC, Danica, AVŠIČ-ŽUPANC, Tatjana, DUH, Darja, **BREZNIK, Matej**, ČEBULC, Gorazd, FAFANGEL, Mario, FATUR, Tanja, HROVATIN, Breda, KALAN, Katja, LEVIČNIK-STEZINAR, Snežna, LOVREC, Milan, MALI, Polonca, MALOVRH, Tadej, PERHARIČ, Lucija, RECEK, Marjeta, SOČAN, Maja, STRLE, Franc, RAČNIK, Joško, TERNIFI, Vesna, TRILAR, Tomi, VRDELJA, Mitja, ZVER, Jasna, SOČAN, Maja (urednik). Načrt pripravljenosti na pojav virusa Zahodnega Nila v Sloveniji : predlog delovne skupine za leto 2015. Ljubljana: Nacionalni inštitut za javno zdravje, 2015. ISBN 978-961-6911-67-2.
14. **BREZNIK, Matej**, KMETEC, Vojko, KRANJC, Andreja, KREFT, Samo, KRISTL, Albin, OSREDKAR, Joško, PETERLIN-MAŠIČ, Lucija, PLANINŠEK, Odon, PUKL, Marko, URLEB, Uroš, ZEGA, Anamarija, KIKELJ, Danijel (urednik). Vaje iz instrumentalne farmacevtske analize. Ljubljana: Fakulteta za farmacijo, 2003.
15. KIKELJ, Danijel, PETERLIN-MAŠIČ, Lucija, MARINKO, Petra, **BREZNIK, Matej**, STEGNAR, Mojca, TRAMPUŠ-BAKIJA, Alenka, FORTUNA LUŽAR, Marijana. Thrombin inhibitors : patent : US 7112590 (B2), 2006-09-26. Alexandria: United States Patent and Trademark Office, 2006.