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Scientific Tracks & Abstracts

Day 1


Biopharma 2016

Hiroyuki Matsuda et al., J Bioequiv Availab 2016, 8:6 (Suppl)
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Search of co-solvents of poorly water-soluble bioactive compounds in natural products on the basis of the solubility measurements

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The object of this study is to search a suitable co-solvent of poorly water-soluble bioactive compounds in natural products on the basis of the solubility measurements. In this study, curcumin (diferuloymethane), the Indian solid gold, the major active component of turmetic, was selected as a model bioactive compound. Curcumin is used as a spice in curry and as a coloring agent in yellow mustards, cosmetics, and pharmaceuticals. It has attracted great interest because of its antioxidant, anti-inflammatory, and potential cancer chemopreventive activities. However, the major problem with curcumin is its extremely low solubility in aquous solution and poor bioavailability. If addition of a suitable co-solvent makes an enhancement of solubilities of curcumin, it would be useful for the development of drug or functional food which an efficient systemic absorption is available. In this work, several β-CD derivatives, e.g., 2-hydroxypropyl- (2-HP-), sulfobutyl ether (SBE-), and methyl- (M-) β-CDs, were investigated as a co-solvent. The solubilities of curcumin in water + CD mixed solvents, and a suitable co-solvent for an enhancement of the solubilities in curcumin was examined. The solubilities of curcumin in water + CD mixed solvents at 298.15 K were determined using high-performance liquid chromatography (HPLC). Enhancement in the solubility of curcumin could be achieved in all β-CD derivatives. Maximum solubilization shows M-β-CD, and follows SBE-β-CD and 2-HP-β-CD. Stability constants kc were evaluated by Takeru Higuchi-Konnors solubility method. The order of the determined stability constants were M-β-CD > SBE-β-CD > 2-HP-β-CD.

Biography

Hiroyuki Matsuda has completed his PhD from Nihon University. His research field is Chemical Engineering Thermodynamics. He is the Associate Professor of Nihon University. He has published more than 30 papers in reputed journals.

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Notes:

Matteo Micucci et al., J Bioequiv Availab 2016, 8:6 (Suppl)
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Acacia catechu Willd extract: A nutraceutical approach to gastrointestinal pathologies

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Gastro-intestinal infections constitute important emerging and re-emerging infective worldwide diseases. They are mostly endemic and show a heterogeneous aetiology. Most water-borne diseases caused by microorganisms induce diarrhoea and determine about 5 million deaths per year. The research on anti-diarrheal tools should be focused on the evaluation of substances and chemically charachterized phytocomplexes able to affect intestinal motility and to exert a prebiotic action. Several plants, such as *Castanea sativa* Mill., *Sanseviera liberica* Gerome & Labroy, have been shown to inhibit gut peristalsis, through several mechanisms. Furthermore, disparate classes of natural compounds including hydrolysable tannins and flavonoids, restore intestinal functionality, affecting different molecular networks influencing each other's. *Acacia catechu* Willd extract (ACE) has been used in Indian Traditional Medicine to manage several diseases including diarrhoea and other gastrointestinal ailments. This extract was shown to contain high amounts of flavonoids, in particular flavan-3-ols. Furthermore, in vitro biological assays were exerted, using tissues from guinea pigs, to assess ACE effects towards induced and spontaneous intestinal smooth muscle contractility. The results demonstrated that ACE reducecs spontaneous and induced colon and ileal smooth muscle contractility via inhibiting muscarinic and histaminergic receptors. Also ACE effects against several pathogenic and non pathogenic bacteria were tested, showing a selective antibacterial activity towards pathogenic strains including, *Staphylococcus aureus*, Gram-negative *Escherichia coli, Salmonella spp., Campilobacter*, without inhibiting. These findings suggest that Acacia may represent a nutraceutical option to manage diarrheal infectious and non infectious disesases.

Biography

Matteo Micucci has completed his PhD from Bologna University and continues his research focused on Medicinal Chemisrty and Nutraceuticals at Department of Pharmacy and Biotechnology, University of Bologna. He had spent three months period, as visiting PhD Student, in the Research Laboratory of Medicinal Chemistry of De Montfort University (DMU), Leicester, UK. He has published 19 papers in reputed journals and is Science Adviser in the field of Nutraceuticals, Alternative and Complementary Medicines, at Segreteria Particolare of a Senator of the Italian Republic, from October 12th, 2015 till date.

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Investigation of the biochemical mechanism of action of antioxidants in the prevention of cancer

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Background: Cancer refers to a group of diseases that are associated with a disturbance in the control of cell growth and metabolism. Indeed, the unbalanced control of cellular proliferation is a primary characteristic of cancer cells and, as such, any molecule capable of inhibiting cancer cell proliferation may also be useful as a potential chemo-preventive agent. Throughout history, antioxidants have been the most significant source of anticancer and chemopreventing agents. More than 1,000 different phytochemicals are already proved to possess interesting chemopreventing activities. Antioxidants consist of a wide variety of biologically active phytochemicals including phenolics, flavonoids, carotenoids, etc., that have been shown to suppress early and late stages of carcinogenesis.

Objective: To review recent biochemical and molecular mechanisms, in relation to natural and synthetic chemopreventing substances (antioxidants) for cancer control and management.

Major Findings: Antioxidants exert anticancer effects via a variety of mechanisms, including removal of carcinogenic agents, modulation of cancer cell signaling and cell cycle progression, promotion of apoptosis and modulation of enzymatic activities.

Conclusion: This review provides an updated and comprehensive overview on the anticancer effects of antioxidants *in-vitro* and *in-vivo* animal models including recent intervention studies. Finally, possible mechanisms of action involving antioxidant and pro-oxidant activity as well as interference with cellular functions are discussed.

Biography

Kissi Mudie has completed his MSc in Medical Biochemistry from Addis Ababa University, School of Medicine. He is the Director of National Clinical Chemistry Laboratory, Ethiopian Public Health Institute. He has published more than 14 papers in reputed journals and has been serving as an Associate Researcher.

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Protective efficacy of *Emblica officinalis* Linn. against radiation and lead induced qualitative, quantitative and biochemical alterations in mouse testes

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In today's changing global scenario, ionizing radiation is considered as most potent cause of oxidative stress mediated by free radical flux which induces severe damage at various hierarchical levels in the organization in the living organisms. Testis is a highly prolific tissue with fast cellular renewal and poor antioxidant defense; therefore, it becomes an easy target for the radiation- induced free radicals that have long been suggested as major cause of male infertility. Radiation causes deleterious effects in all forms of life due to increasing utilization and production of modern technology, a simultaneous exposure of organisms to heavy metals is also unavoidable. These heavy metals become toxic when present in large quantities, with increasing the industrial revolution and industrial waste, the emission of lead has increased into the environment. Thus concomitant exposure to lead acetate and ionizing radiation might produce deleterious effect upon biological system. The total environmental burden of toxicants may have greater effect as against their individual impact as expected by their nature. So interaction between radiation and other toxicants represents a field of great potential importance. In the recent years, immense interest has been developed in the field of chemoprotection against radiation and heavy metals induced changes. In view of the potential for practical application, a variety of compounds are being tested for their radioprotective activities. Among these, *Emblica* holds a great promise. In light of the above, the present study was aimed to evaluate the protective effect of *Emblica officinalis* extract (ECE) against radiation and lead induced qualitative, quantitative and biochemical alterations in the testes of Swiss albino mice. The animals were exposed to 3.0 and 6.0 Gy of gamma rays with or without lead acetate treatment. The *Emblica* was administered seven days prior to irradiation or lead acetate treatment. The animals were divided into seven groups. The nondrug treated control groups were administered lead acetate and exposed to irradiation whereas the experimental groups were given Emblica seven days prior to irradiation or lead acetate treatment. Irradiation resulted into significant decrease in the frequency of different spermatogenic cell counts along with severe histo-pathological lesions up to 14th day in control animals and day-14 in experimental animals thereafter, recovery followed towards the normal architecture. ECE pre-treatment effectively prevented radiation induced end of experimentation. Furthermore, ECE administration inhibited radiation and lead induced changes in the testes of mice. These observations signify that the *Emblica officinalis* extract can be used as an efficient radio- protector against radiation mediated qualitative, quantitative and biochemical alterations in testes.

Biography

R K Purohit at present is working as Professor of Zoology in Govt. Dungar College, Bikaner (Rajasthan), India. He has 25 five years of teaching and research experience. He has published around 40 research papers in journals of international repute. He has attended dozens of national and international conferences and also presented his papers. He has also chaired the sessions in many international conferences. He has produced 19 PhDs and 20 MPhil scholars under his able supervision. He has visited Singapore, Malaysia and Japan. He is the recipient of many national and international awards. He has organized one "National Conference on Herbal Radioprotection" in the year 2004 (October, 2004) and an International conference in January 2012. He is the life member of many academic societies. At present, he is holding the prestigious status of National Secretary, Indian Society for Radiation Biology who is specially working in the field of herbal radioprotection.

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Jeanne Leblond, J Bioequiv Availab 2016, 8:6 (Suppl)
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Switchable lipids for pH-sensitive siRNA delivery

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RNA interference provides a targeted approach for silencing gene expression that may prove beneficial in the treatment of diseases such as cancer and genetic disorders. To ensure effective knockdown, siRNA must be entrapped and efficiently conveyed into the cytoplasm of cells. These hydrophilic nucleic acids have to cross the lipid-rich plasmatic and/or endosomal membrane, without being degraded into lysosomes. We have developed new pH-sensitive lipids able to change conformation upon protonation at endosomal pH values, leading to the disruption of the lipidic bilayer and thus to the fast release of the nucleic acids into the cytosol. The objective of this work was to design a fast-responding system at pH 5 while remaining stable at blood pH value and during storage. This was achieved by the design and synthesis of a series of switchable lipids, and their incorporation into lipid nano-particle (LNP) composition. LNP complexed with siRNA exhibited high silencing efficiency, reaching up to 10% on HeLa cells, very similar to a commercial agent, with lower toxicity. Negative controls demonstrated that the improved efficiency was due to the conformational switch of the lipids. *In vitro* transfection potential was confirmed on various cells lines (HeLa, A549, Huh-7) and siRNA targets (GFP, PCSK9, survivin). *In vivo* applications are currently focused on liver disease, such as hypercholesterolemia. Indeed, liver targeting has been shown in mice by fluorescence imaging. This system has recently been able to reduce the LDL as well as HDL cholesterol blood levels of mice after a single I.V. injection of LNP/siRNA.

Biography

Jeanne Leblond has completed his PhD from Université Paris VI and Post-doctoral studies from faculty of Pharmacy of University of Montréal. She is Assistant Professor at the Faculty of Pharmacy since 2011. She is the Director of the research axis “Drug Formulation and Analysis” and has trained over 20 students in 5 years. She has published 13 research articles, 1 book chapter, most of them in journal with IF higher than 4.5.

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Epigenetic change of genome by peptide bioregulators in extreme old age

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Purpose: The objective of the present investigation is to study the modification of chromosome (total heterochromatin, constitutive and facultative heterochromatin) under the influence of peptide bioregulators (Ala-Glu-Asp-Gly, Ala-Glu-Asp-Pro, Lus-Glu-Asp-Ala and Lys-Glu) and heavy metal in cultured lymphocytes derived from old individuals.

Methods: The level of total heterochromatin - identified by the method of differential scanning microcalorimetry; the level of facultative heterochromatin – by the method of sister chromatid exchanges (SCE), level of satellite stalk and C-heterochromatin under the combined effect of bioregulators and Co Cl2 have been studied in lymphocyte cultures from individuals at the age of 80 and over.

Results: The results showed that: 1) epigenetics processes – progressive heterochromatinization of total, constitutive (pericentromeric, telomeric and NOR heterochromatin) and facultative heterochromatin occurred with aging; 2) peptide bioregulators induce deheterochromatinization of chromosomes in old age; 3) higher level of SCEs (deheterochromatinization) were registered in precentromeric and telomeric heterochromatin upon combined effect of Co ions and peptide bioregulators.

Conclusions: The proposed genetic mechanism responsible for constitutive and facultative heterochromatin epigenetic change (hetero- and deheterochromatinization pericentromeric and telomeric region) of old age may lead to the development of therapeutic treat.

Biography

Lezhava T has discovered that the progressive heterochromatinization occurs in aging and his scientific works are generally dedicated to the problem Genetics of Aging. He delivers lectures in Genetics, Human Genetics with the Fundamentals of Molecular Genetics, Medicine Genetics and Evolution of Genome. He is a Member of Editorial Board of journals like: *"Georgian Medical News"; "Gerontology and Geriatric Research"* (NJ, USA); *Jacobs Journal of Gerontology* (Texas, USA); Edition "Inter ging" and *Journal of Deutscher Wissenschaftsherold* (Germany); *Journal of Biomedicina* (Russia). He is a member of the International Association and USA of Biomedical Gerontology, President of Georgian Gerontology Association, Head of Georgian Human Genetic Association and member of several local and foreign Scientific Academies.

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Upendra L Patel, J Bioequiv Availab 2016, 8:6 (Suppl)
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Design and evaluation of press coated pulsatile release tablets of Prednisolone

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To formulate and evaluate a press coated pulsatile release tablets of prednisolone using an admixture of hydrophilic polymer, i.e., low substituted hydroxy propyl cellulose (L-HPC) and hydrophobic polymer, i.e., ethyl cellulose (Ethocel 10 cps) in order to achieve a pre-determined lag time for chronotherapy of rheumatoid arthritis. The press coated pulsatile tablets containing prednisolone in the inner core were prepared by compression coating with L-HPC and Ethocel 10 cps as the outer layer in different ratios. The effect of polymer ratio and weight gain of the outer layer on lag time of drug release was investigated using 3^2 full factorial design. The parameters determined were tablet hardness, friability, drug content, lag time, *in vitro* dissolution. The release profile of the press coated tablet exhibited a distinct lag time before burst release of prednisolone. Lag time was dependent on the ratio of L-HPC/Ethocel 10 cps and weight gain in outer shell. The lag time was from 1 to 10 hr and could be modulated as it decreased as the amount of L-HPC in the outer layer increased. A surface plots are also presented to graphically represent the effect of independent variables on the lag time. The validity of generated mathematical model was tested by preparing checkpoint formulation. Formulation PCPT7 with L-HPC/Ethocel 10 cps (10:90) and weight gain 300 mg showing predetermined lag time of 5 hr prior to burst release of the drug from the press coated tablet was taken as the optimized formulation.

Biography

Upendra L Patel has completed his PhD from Sardar Patel University, Anand, Gujarat, India in 2010. He is the Head of Department & Associate Professor in Department of Pharmaceutics & Pharmaceutical Technology in Arihant School of Pharmacy & BRI, Gujarat, India. His area of research is formulation and evaluation of controlled drug delivery formulations. He has guided more than 25 MPharm students. He has published more than 40 papers in reputed journals and one book *"Dispensing Pharmacy & Drug Store Management"*. He is life time member of Gujarat Pharmacy Teacher Associations.

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Scientific Tracks & Abstracts

Day 2


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New and old technologies for the cosmetic innovation learning from the pharmaceutical world and balancing through the regulatory requirements

Lorella Ragni
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In the cosmetic field consumers are expecting the latest technology advances to be incorporated into innovative formulations, both in terms of active ingredients (entering the perimeter of cosmeceutics) and in terms of delivery technologies. The recent regulatory framework growing araound the cosmetic world, both in the EMA and FDA perimeters, is somewhat changing the way of pursuing innovation in this field. Cosmetics formulators today are looking more and more to mutuate technologies from the pharmaceutical world, looking both at the delivery sisthems and at the new functional ingredients. This cross-contamination between pharmaceutical and cosmeceutical technologies is very important to promote innovation in this field, and can also maximize the return of the research investment for companies that have a pipeline involving both types of products. However, the challenge is not only to respect regulatory requirements that are constantly evolving in the cosmetic and cosmeceutics world, but also to offer new, smart systems that are able to deliver the active ingredients to one or more skin layers minimizing the systemic adsorption.

Biography

Lorella Ragni graduated in Chemistry and Pharmaceutical Science at Bologna University Italy. Soon after the degree she attended the Master in Cosmetic Product Development at Ferrara University Italy. After a short experience in 1988 as researcher in Synthetic Chemistry at Ancona University Italy, since 1989 she has been working in Angelini covering different positions in the Development Product Department. From 2001 to present she took over the position of Head of Formulation Department. During her working experience she has been the leader of several scientific groups of formulators and analysts for the development of solid, liquid, semisolid pharmaceutical products and new drug delivery systems. In the last five years she extended her range of activity in the formulation development of Food Supplements, Cosmetics and Medical Device for European Market. She constantly supports the Company in the research and evaluation of new technologies for the feeding of project pipeline and she was the author of several European and Worldwide Patents.

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Sihem Bihorel, J Bioequiv Availab 2016, 8:6 (Suppl)
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Novel tri-functional lipid nanoparticles for immunotherapy of resistant HER2-positive breast

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Purpose: Breast cancer (BC) is the second leading cause of cancer deaths in women, and about 25% of BCs have overexpression of the HER2 receptor. Although HER2 targeted therapies have shown considerable improvement in HER2-positive BC patients' outcome, treatment resistance remains a clinical challenge. Here, we sought to develop and evaluate a novel tri-functional lipid nanoparticulate (TFLP) drug delivery system that overcomes HER2 treatment resistance by dually targeting HER2 on BC cells and CD3 receptors on cytotoxic T-lymphocytes (CTLs).

Material & Methods: Anti-HER2 (Trastuzumab) and anti-CD3 (OKT-3) antibodies were conjugated to lipid nanoparticles by the micelle-transfer method, and the resulting formulation was purified by dextran gradient ultra-centrifugation. Targeted lipid nanoparticles were formulated with a fluorescent lipophilic dye, DiD, for studying receptor binding and internalization. Studies were conducted with HER2-positive BT474 cells and CD3-positive Jurkat cells using flow cytometry analyses. Doxorubicin HCl (DXR) was encapsulated in the nanoparticles by the remote-loading technique for cell-kill experiments. *In vitro* cell-kill studies were conducted by co-culturing BT474 as the target cells, and peripheral blood mononuclear cells as the effector cells, at varying ratios.

Results: Purified formulations were successfully characterized for conjugation by determining protein to lipid ratio. Flow cytometry analyses demonstrated successful cell binding and/or internalization of the TFLP with both the HER2 and CD3-positive cell lines. Moreover, these dual-targeted nanoparticles were able to retarget T cells to kill HER2 positive BC cells, and showed improved efficacy compared to non-targeted and plain HER2-targeted formulations *in vitro*.

Conclusion: A novel TFLP drug delivery system that targets HER2 receptors on tumor cells, CD3 on CTLs, and is able to slowly release DXR was successfully developed and evaluated *in vitro* on HER2 overexpressing BC cells. Our findings showed great promise at overcoming resistance to present HER2 targeted BC therapies, and may translate into improved anti-tumor activity clinically compared to other treatment options.

Biography

Sihem Bihorel (Ait-Oudhia) utilizes quantitative systems pharmacology approaches to guide the development of new therapies and the identification of promising combination therapies as well as of novel biomarkers in Oncology. She integrates quantitative systems pharmacology with PK/PD modeling and simulation to advance drug discovery and development, and leverage the understanding of drugs action which holds great promise to facilitate translational research. Her research is also focused on investigating how priming solid tumors with a pro-apoptotic agent then combining a subsequent large protein therapeutic and an antiagiogenic agent can defeat drug resistance and treatment failure in cancer and further enhance the efficacy of targeted anticancer agents, and translating these findings toward clinical settings. Prior to this position, she held the position of Research Assistant Professor at the State University of New York at Buffalo where she was also trained as a Post-doc and received her PhD from the same.

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The importance of Dexamethasone preoperatively for the prevention of cognitive dysfunction

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Background: Postoperative cognitive dysfunction (POCD) is a multifactorial adverse event most frequently in elderly patients or people aged over 60 years, with neurological and psychiatric diseases. This study evaluated the effect of dexamethasone on POCD incidence after non-cardiac surgery and general anesthesia.

Methods: 140 patients (ASA I–II; age 60–87 years) took part in a prospective randomized study involving the administration or not of 8 mg of IV dexamethasone before deep or superficial anesthesia according to bispectral index. Neuropsychological tests were applied preoperatively and at 3rd, 7th, 21st, 90th and 180th days after surgery and compared with normative data. S100β was evaluated before and 12 hours after induction of anesthesia. Linear regression with inference based on the generalized estimating equations (GEE) method was applied, followed by the *post-hoc* Bonferroni test considering $P<0.05$ as significant.

Results: On the 3rd postoperative day, POCD was diagnosed in 25.2% of patients receiving dexamethasone plus deep anesthesia, 15.3% of the dexamethasone plus superficial anesthesia group, 68.2% of the deep anesthesia group and 27.2% of the superficial anesthesia group ($p<0.0001$). Neuropsychological tests showed that dexamethasone plus superficial anesthesia decreased the incidence of POCD, especially memory, attention and executive function. The administration of dexamethasone prevented the postoperative increase in S100β serum levels ($p<0.002$).

Conclusion: Dexamethasone can minimize the incidence of POCD in elderly patients undergoing non-cardiac surgery, especially when associated with superficial anesthesia. The effect of dexamethasone on S100β levels might be related with some degree of neuroprotection.

Biography

Livia Stocco Sanches Valentin has completed her PhD from University of São Paulo School of Medicine- FMUSP and Post-doctoral from Harvard Medical School; David Geffen School of Medicine at UCLA; Cleveland Clinic Lerner College of Medicine of Case Western University; University of Copenhagen; Utrecht University; Max Planck Institute and Karolinska Institute as a multicenter study. She is the Principal Investigator of the RCT Evaluation of POCD through the MentalPlus® digital game. She has published papers in *Anesthesia* and *Neuropsychology* journals and has been serving as an Editorial Board Member of an indexed journal and reviewer of journal about anesthesiology and neuroscience.

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Maysaa Ch Al Mohammedawi et al., J Bioequiv Availab 2016, 8:6 (Suppl)
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Nanoparticles loaded with 5-Fluorouracil, Leucovorin and Bovine Lactoferrin as drug delivery carriers

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Encapsulation of drugs into nanoparticles (NPs) has become a promising approach for improving the efficacy of antitumor drugs. This study evaluates the cytotoxic effect of nanoformulated antitumor drug 5-fluorouracil (5-FU), alone and combined with leucovorin (LV) or iron saturated bovine lactoferrin (Fe-bLf) by, encapsulating into FDA approved biodegradable polymer poly ε-caprolactone (PCL) NPs. The spherical NPs were 200-300 ± 2.9 nm in size and had drug loading capacities of 90% (5-FU-PCL), 60% (5-FU-LV-PCL) and 80% (5-FU-Fe-bLf-PCL). Drug release of 5-FU and LV after 96 h reached 98.6 % and 99.89%, respectively; Fe-bLf release was 82.28% after 96 h. Both MTT and TUNEL assay results showed that the multi-combinatorial NPs had cytotoxicity as high as 97% and could induce apoptosis in human colon cancer cell lines (Coca-2 and SW480), but had no effect on normal FHs 74 Int cells. These findings highlight the novelty and promise of this drug delivery system, and the results warrant further evaluation in suitable animal model for its future clinical applications.

Biography

Maysaa Ch Al Mohammedawi has completed her MSc and PhD in Medical Biotechnology from the Department of Biotechnology at Al Nahrain University, Baghdad, Iraq. She became a faculty member and group leader of Medical Biotechnology research over there. She worked on molecular analysis of infectious disease, studies on the virulence factors of the pathogens, and screening anticancer agents among bacterial components. In 2012, she was awarded MoHER (Iraq) career development fellowship. Recently, join the IIE-SRF (US) fellowship at School of Medicine, Deakin University, Australia. Her studies focus on improving the in vitro drug delivery system of antitumor agents toward colon cancer.

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Comparative bioequivalence study of two Rivaroxaban formulations in Iranian healthy volunteers

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[2]Islamic Azad University, Iran
[3]Veterinary Organization, Iran

It is a factor Xa inhibitor whose potent anticoagulant and antithrombotic effects have been demonstrated. This study was designed to evaluate the pharmacokinetics of a new generic formulation of rivaroxaban compared with a brand in healthy Iranian volunteers. Twenty-eight healthy volunteers enrolled in this study. This study employed a randomized, single-dose, two-way crossover method using oral tablets of either Axabin® or Xarelto®, as the test drug and reference drug, respectively. Two tablets (2×10 mg) were administered with 240 ml water. Blood samples were gathered at the following times: 0 hour (predose), and 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 24, and 30 hours after drug administration. To provide an accurate analysis, rivaroxaban plasma concentrations were determined by an UHPLC-MS/MS. The optimum separation was performed with a C18 column using acetonitrile and 10mM ammonium acetate (pH = 3, 70:30, v/v) as a mobile phase, at a flow rate of 0.3 ml/min. Precipitation of proteins was employed for extraction of rivaroxaban from the plasma samples. The quantification range for rivaroxaban was 2.5–600 ng.ml-1. According to FDA guidelines, the bioequivalence assessment's acceptable range is 80–125% at a 90% confidence interval (CI) for the mean ratios of test/reference formulation of the pharmacokinetic parameters. The 90% CI of parameters were AUC0-30 (82.02–98.31), AUC0-inf (82.4-100.34), and C_{max} (82.7–104.49). Therefore, the results proved the claim that the two formulations of rivaroxaban are bioequivalent.

Biography

Mohammad-Reza Rouini has completed his PhD from Tehran University of Medical Sciences and Post-doctoral studies from Ottawa University. He is the Director of Biopharmaceutics Lab at Faculty of Pharmacy. He has published more than 100 papers in reputed journals and has been serving as an Editorial Board Member of DARU.

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Omodamiro O D et al., J Bioequiv Availab 2016, 8:6 (Suppl)
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In vitro antioxidant activity and hypolipidemic effects of an ethanol extract of *Amaranthus viridis* leaves on hyperlipidemic Wistar Albino rats

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Amaranthus viridis Linn. (AV), commonly known as 'Slender or Green Amaranth' in English, is a multinational genus of herbs. Several species of are often considered as weeds, as leafy vegetables, cereals and ornamentals. Traditionally, an infusion of the plant (leaves and roots) is used to treat dysentery and epilepsy in children, purify blood, reduce inflammation, hemorrhoids, reduce labor pain and improve appetite in parts of Africa and India. The present study was designed to evaluate the *In vitro* antioxidant activity and hypolipidemic effect of an ethanol extract of AV leaves (EEAVL) in Wistar albino rats and mice as experimental models. Acute toxicity (LD50) of EEAVL was studied in mice using standard method. The result showed a LD50 of 353.6 mg/kg of the extract. Fourteen (14) Wistar albino rats of both sexes were divided randomly into seven (7) groups of two animals, each subjected to different treatment for 14 days. Group A was the non-high fat diet control; Group B was the high fat diet-induced control; Group C received 20 mg/kg of Simvastatin, a standard lipid lowering drug; Group D to G received 250 mg/kg, 125 mg/kg, 62.25 mg/kg and 31.13 mg/kg BW respectively of EEAVL of which all were still maintained on their induced diet. At the end of the treatment, the lipid profile and body weight were estimated and compared with the Simvastatin treated control group. The result showed a significant ($p<0.05$) decrease in T-Cholesterol, Triglyceride and LDL-C ($p>0.05$) while HDL-C was increased at the doses studied. EEAVL also caused a decrease in the rate of weight gain. In the *in-vitro* antioxidant test, there was a concentration dependent increase in the (%) scavenging activity when compared with the Vitamin C (control) for 1, 1-diphenyl-2-picrylhydrazyl (DPPH), Nitric oxide and anti-lipid peroxidation activity of AVL. The results showed no significant difference at higher concentrations when compared to the control. On a comparative basis, the measure of the antioxidant effectiveness of the extract showed better activity in quenching Nitric oxide radical with IC50 values of 72 mg/ml compared to Lipid peroxidation radicals (78mg/ml) and DPPH radicals (108 mg/ml). The result have shown that Amaranthus viridis L, a traditional folklore medicinal plant has *in vitro* antioxidant potentials and hypolipidemic effect which may provide therapeutic potentials in the management of Cardiovascular diseases, diabetes and their complications which might be caused by free radical generation and hyperlipidemia.

Biography

Omodamiro O D holds a PhD in Pharmacology from College of Medicine and Health sciences, Abia State University Uturu Abia State Nigeria. He is currently a senior Lecturer in the Pharmacology Unit of Department of Biochemistry, Micheal Okpara University of Agriculture Umudike Abia State Nigeria. He has published over 30 research papers in international reputable journals. His areas of research are cardiovascular/endocrine pharmacology, ethnopharmacology, renal pharmacology and medicinal plants.

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