PHYTOMEDICINE

International Journal of Phytotherapy and Phytopharmacology

AUTHOR INFORMATION PACK

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DESCRIPTION

Phytomedicine is primarily a therapy-oriented Journal. *Phytomedicine* publishes innovative studies on efficacy, safety, quality and mechanisms of action of specified plant extracts, phytopharmaceuticals and their isolated constituents. This includes *clinical, pharmacological, pharmacokinetic, and toxicological studies* of specified herbal medicinal products, herbal preparations and purified compounds which have a defined and consistent quality assuring reproducible pharmacological activity.

Phytomedicine was founded in 1994 to focus and stimulate research in this particular field and to set internationally accepted scientific standards for pharmacological studies, proof of clinical efficacy and safety of phytomedicines.

The main aims of *Phytomedicine* are associated with the integration of phytopreparations into conventional/official medicine.

The journal covers the following sections:

Clinical pharmacology and toxicology (randomized, placebo controlled, double blind, and observational open label studies)Behavioural, mental, affective, and stress-associated disordersAge-associated disordersNeuropharmacology Endocrine pharmacology Metabolic syndrome and obesityCancerImmunopharmacology, inflammationInfectious diseasesPulmonary, gastrointestinal, cardiovascular and urogenital diseasesSystems biologySafety assessment, pre-clinical toxicology, interaction with drugs and adverse events of herbal preparations Pharmacokinetic of natural compoundsStandardization of herbal preparationsLegislation of botanicalsInvited reviews

The directions of *Phytomedicine* are known to provide profound scientific background in Herbal Medicinal Products, their reproducible Quality and evidence based therapeutic efficacy. Since then quality criteria and standardization methods were defined and the European Medical Agency has elaborated numerous guidelines for the conduction of clinical studies and preparation of Herbal Medicinal Products. In total 107 ESCOP monographs have been produced and submitted to EMA. Many new analytical methods and instruments were implemented both for analysis and standardization of herbal Substances, herbal preparations and their bioassays and tremendous work has been carried out to remain aligned with these intentions during the last 18 years.

Nowadays important topics remain to be approached, such as harmonization of the regulatory frameworks in Europe, America, Asia and Australia or the legislation of various "botanicals", where strict differentiation of requirements for health claims of herbal medicinal product, dietary supplements and nutraceuticals are required.

AUDIENCE

Pharmacologists, toxicologists, pharmacists, pharmacognosists, phytotherapists (clinicians), biochemists, botanists, general practitioners

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INTRODUCTION

PHYTOMEDICINE

International Journal of Phytotherapy and Phytopharmacology

Scope

Phytomedicine is primarily a therapy-oriented Journal, which publishes innovative studies on efficacy, safety, quality and mechanisms of action of specified plant extracts, phytopharmaceuticals and their purified constituents. This includes clinical and preclinical studies of properly standardized herbal medicinal products, herbal preparations and isolated compounds, which have reproducible pharmacological activity.

The journal covers the following sections: Trends in Phytopharmacology: innovative technologies and emerging concepts - Reviews Clinical pharmacology and toxicology Pre-clinical pharmacology and toxicology Mechanisms of action of herbal medicines and their active constituents Neuropharmacology Endocrine pharmacology Cancer Inflammation Infectious diseases Cardiovascular diseases Ageing associated disorders Quality of Herbal preparations/botanicals: adulteration, standardization, analysis Legislation of Herbal preparations/botanicals Current issues in Phytomedicine research (various topics which are not covered in all other volumes).

BEFORE YOU BEGIN

Article requirements

Please note the following requirements for consideration of an article, upon submitting your manuscript:

1. Is your article within the scope of Phytomedicine?
Your article must meet the scope of Phytomedicine (please see above). **Articles that are not in the scope, will be rejected immediately!** Articles on the isolation and structure elucidation of novel bioactive compounds or the development of new analytical methods do not fall into the scope of Phytomedicine. However, pharmacological and clinical studies of novel natural products, where new compounds or methods of analysis of active of pharmaceutical ingredients in herbal preparations and biological fluids and tissues are reported (e.g. in pharmacokinetic studies), are welcome. Dietary Supplements, "Botanicals" or "Functional Food" are not within the scope of Phytomedicine unless they are specified/standardized and pharmacologically investigated analogues to herbal drugs and if the evidence presented is comparable to therapeutic outcomes with a positive control. Studies on pure compounds are not accepted if their origin is not clearly related to the plant kingdom. Pharmacological studies of isolated compounds in various forms (salts, ethers, etc.), which do not exist in nature are out of scope of Phytomedicine. Screening results of a large number of plant extracts or plant constituents for pharmacological activities will not be considered unless they are focused on those plants or constituents which show superior activities in comparison with generally accepted positive (reference) compounds.

2. Does your article comply with the standard requirements of Phytomedicine?
Your article must meet the criteria assuring reproducible quality and efficacy of herbal preparations.
Plant name and herbal substance
Latin binomial name and the author, local name and English name and plant part(s) used must by specified for all plants used in the study. It should be stated that the plant name has been checked with http://www.theplantlist.org. The authentication of fresh plants or dried herbal drugs, including those of formulas, must be carried out by means of macroscopic and/or microscopic, molecular biological, chemical, chromatographic and/or other suitable pharmacognostic methods. Voucher specimens of plant materials used for all studies must be deposited and identified with a voucher number, the date and location of collection. The plant material may derive from natural origin, from cultivated plants, or from an herbal drug market. In case of commercially procured material the source, batch number, and quality control data should be specified. All scientific names of the plants must be written in italics through the whole manuscript! Herbal medicinal products and herbal extracts
Herbal medicinal products or herbal preparations must be declared in accordance to EMA guidelines. In particular, herbal extracts must be clearly and comprehensively described with respect to the plant part used, the drug extract ratio, type and concentration of extraction solvent, extraction

conditions etc. They must be sufficiently characterized (e.g. by HPLC fingerprints) and specified for the content of marker compounds to ensure a consistent quality and reproducible pharmacological activity. The choice of marker must be justified. The analytical methods have to be validated for selectivity, accuracy and precision and briefly described, providing the most important information necessary to obtain reproducible results. Traditional and commercial names of herbal preparations should be mentioned in the Introduction of the manuscript, but not in the title. Phytomedicine accepts only international standard terminology – binomial Latin names of the plants and their combinations.
Herbal combinations
Studies with herbal drug combinations (e.g. 2-5 plants) will be accepted only if each herbal drug undergo the same authentication and standardization process as described above, each single herbal extracts is HPLC fingerprinted and relevant marker constituents are quantified before and after the extracts are mixed. A 3-D-HPLC-profile of the multiherbal drug combination must be provided. Authors must clearly demonstrate which analytical marker specifically indicates on the presence each of herbal ingredients in the combination.Additionally, we encourage the use other relevant and validated physiological, biological, or biochemical methods, which ensure reproducible pharmacological activity of multi-herbal drug combinations.
Chemicals, phytochemicals and other purified compounds For purified compounds, please provide chemical names using relevant information from the NCBI PubChem which can be found on the website http://www.ncbi.nlm.nih.gov/pccompound. In studies with purified compounds the evidences of their purity (13C NMR or HPLC peak purity test) are required.

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Approved C. elegans symbols are provided by Caenorhabditis Genetics Center: http://www.cbs.unmn.edu/CGC/Nomenclature/no menguid.htm For approved S. cerevisiae and S. pombe symbols see http://yeastgenome.org/help/yeastGeneNomenclature.shtml and http://www.sanger.ac.uk/Projects/S_pombe/SP_Name_FAQ.shtml, respectively Statistical analysis
Statistical hypothesis and methods should be described in detail. Actual P values should be used unless less than 0.001. Reporting of 95% confidence intervals is encouraged. The choice of appropriate parametric or nonparametric tools has to be justified. Refer to B.S. Evererett. Statistical Methods for Medica Investigations, Oxford University Press, New York, 1989.

3. Is your article approaching new findings?
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4. Is your article relevant to clinical medicine?
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of Reporting Trials Statement for Herbal Medicinal Interventions (CONSORT), particularly when it comes to description of study medication, which is a strict requirement of acceptance for Phytomedicine. For guidelines and necessary information, please use the following internet addresses: http://www.consort-statement.org, http://www.consort-statement.org/extensions?ContentWidgetId=557, http://www.consort-statement.org/Media/Default/Downloads/Extensions/CONSORT-Herbal-Interventions.pdf, http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003370.pdf. Use of a CONSORT checklist and flow diagram is recommended for illustration of grouping and flow of patients in all clinical studies, randomized clinical trials as well as other trials. Clinical studies must be approved by an Institutional Ethics Committee or its equivalent. The Methods section must state that the study followed the guidelines of the Declaration of Helsinki and Tokyo for humans!

Requirements for pharmacological studies (in vitro, ex vivo or in vivo): Investigations with animals must state in the Methods section that the research was conducted in accordance with internationally accepted principles for laboratory animal use and care (e.g. European community guidelines/ EEC Directive of 1986 or the US guidelines/ NIH publication). The route of drug administration, different of oral, must be justified. Appropriate and justified statistical methods must be used.Positive controls (reference standards must be included in study design). Many natural compounds are known for their polyvalent (pleiotropic) activities and are only of interest if one or two pharmacological activities are dominant and somehow superior in comparison with generally accepted reference standards/compounds. Their potential therapeutic application must be justified for specified indication. Antimicrobial evaluation of plants are of scientific value only if these plant extracts show superior biological activities in comparison with a synthetic or natural antimicrobial agent standard. It is preferred that in vitro activity (MIC) of an extract in not higher than 100 ìg/ml. For the correct determination of MIC values, standardized methodologies such as those of CLSI or EUCAST are preferred. All articles that are reporting gene expression profiling data (microarray experiments) should comply with the Minimum Information about Microarray Experiments (MIAME, http://www.mged.org/Workgroups/MIAME/miame.html). At least two microarrays should be provided for each experimental condition. Results of selected genes should be validated by a second method (e.g. RT-PCR) or protein data should be provided. In addition functional test (animal experiments/ clinical data) undertaken simultaneously are desirable to allow an appraisement of the biological/ clinical relevance of the data. Alternatively, results of in vivo experiments with comparable dosages can be discussed. The presentation of a sole data collection is not acceptable. Biologically relevant information should be presented. We recommend do not overuse specific names, notions and terms from various theories of traditional medical systems (e.g. TCM, Ayurveda, etc.). That makes articles difficult for perceptions and understanding. The essence of these theories should be translated into internationally accepted scientific theories, while traditional names and terms should be converted to English. Final interpretation of the results of the study must adhere to conventional scientific theories.

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Hyun A Oh[a], Dae-Eung Kim[b], Hyuck Jai Choi[c], Nam Jae Kim[c], and Dong-Hyun Kima[c,*]

[a] Department of Life and Nanopharmaceutical Sciences, College of Pharmacy, Kyung Hee University, 26, Kyungheedae-ro, Dongdaemun-ku, Seoul 130-701, Republic of Korea

[b] Sempio Foods Company, 183, Osongsaengmyung-4ro, Cheongwongun, Chungcheongbukdo 363-954, Republic of Korea

[c] East-West Medical Research Institute, Kyung Hee University Medical Center, 23, Kyungheedae-ro, Dongdaemun-ku, Seoul 130-872, Republic of Korea

[*] Corresponding author
Dong-Hyun Kim, Department of Life and Nanopharmaceutical Sciences, College of Pharmacy, Kyung Hee University, 26, Kyungheedae-ro, Dongdaemun-ku, Seoul 130-701, Republic of Korea
Tel.: +82 2 961 0374; fax: +82 2 957 5030.
E-mail address: dhkim@khu.ac.kr (D.H. Kim).

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Willcox, M.L., Graz, B., Falquet, J., Diakite, C., Giani, S., Diallo, D., 2011. A "reverse pharmacology" approach for developing an anti-malarial phytomedicine. Malaria J. 10 (Suppl. 1), S8.

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