

药物评价研究

YAOWU PINGJIA YANJIU

第44卷 第5期 2021年5月

(月刊)

1978年创刊

主管

天津药物研究院(www.tjipr.com)

主办

天津药物研究院(www.tjipr.com)

中国药学会(www.cpa.org.cn)

编辑出版

《药物评价研究》杂志编辑部

地址：天津市滨海高新区惠仁道306号
(300462)

电话/传真：022-23006822

邮箱：der@tiprpress.com

网址：www.中草药杂志社.中国
www.tiprpress.com

印刷

天津市恒远印刷有限公司

国际标准连续出版物号

ISSN 1674-6376

国内统一连续出版物号

CN 12-1409/R

发行订阅

本刊编辑部

国内定价

每期 30.00 元

全年 360.00 元

出版日期

2021年5月8日

广告发布登记号

BH 2020-01

刊名题字

刘昌孝

本期责任编辑

李红珠

目 次

【专论】

- 909 电子化患者报告结局在新药临床试验疗效评价中的应用
李小贤, 赵 煜, 林 峰, 张子振, 元唯安

- 917 临床试验用药品信息管理专家共识
蔡君龙, 周晶晶, 李晓晖, 胡永芳, 马丽萍, 刘 巧,
王少华, 肖 晟, 朱 莉, 李海俊, 林 梅, 季晓慧,
朱雪琦, 王佳庆, 王 姝, 李 晶, 刁 丽, 郭珊珊,
黄文静, 杨海淼, 曲芯瑶, 邱 艳, 孙梦琦, 王述蓉,
布格拉·米吉提, 刘春丽, 林 阳, 刘利军, 丁 倩,
刘 真, 呼君瑜, 聂明星, 朱露莎, 容颖慈, 唐 蕾,
王 娇, 张翌韦, 梁 欣, 张 毅, 艾俊波, 陈 舟,
曹文忠, 谢朝清, 曹 彩, 黄建英

- 924 单一成分药物有关物质的质量控制研究要点
孙 昱, 郑 蕊, 文海若

【审评规范】

- 931 EMA 简化新型冠状病毒肺炎疫苗和治疗药物说明书及
标签要求介绍
萧惠来

【实验研究】

- 936 四妙勇安汤“异病同治”脱疽、糖尿病和冠心病的网络药理学
作用机制研究
李娟, 张悦健,

李腾腾, 王饶颖, 张媛凤, 王曦廷, 卢 涛

- 949 香砂平胃颗粒对湿阻中焦证大鼠胃肠功能的影响及机制
李 晗, 高云航, 宋 玲, 陈腾飞, 侯红平,
霍 旺, 张广平

- 956 基于 HPLC 指纹图谱结合化学模式识别的黄蛭益肾胶囊
质量控制
薛起梅, 施海蔚,

钱叶飞, 谭 力, 郭 青, 闵春艳

- 964 iv 盐酸左氧氟沙星注射液 Beagle 犬毒动学及毒性研究
张 娜, 房 城, 刘永武, 朴成玉, 董婉茹,
安柏松, 吴修红

- 971 金丝桃苷通过 NOS/NO 系统调控血管内皮影响动脉粥样
硬化进程的实验研究
刘 驰,
闵冬雨, 朱竟赫, 袁 宇, 关晓娇, 胡丽萍

- 978 治咳川贝枇杷滴丸祛痰镇咳药效学评价及对肺组织
Muc5AC 表达的影响
李雪丽, 韩 旭, 王金磊, 庄朋伟, 郭 虹

- 984 罗布麻叶水提取物对链脲佐菌素致糖尿病小鼠的治疗作用
及对肠道 GLP-1 蛋白表达的影响
黄景凤, 王 莉, 何 伟, 刘 磊, 刘小愉,
马福昌, 马 丽, 李治建

- 990 乌拉草总黄酮脂质体凝胶剂的制备工艺研究
苏 婷, 赵 燕, 毕 野, 高羚毓, 贾欣欣,
包 正, 李 鹤, 邱智东

- 997 加味生脉散对脓毒症大鼠急性肾损伤的保护作用研究
王 帅, 万晓刚, 邱潮兵, 易智彪, 吴永刚,
陈仁山, 姚海魂, 肖彩宏, 李泽华

- 1004 GP73 通过 EMT 调节肝癌细胞对奥沙利铂耐药
刘晓冬, 武晓萌, 王 冬, 康 乐, 张 琦

【临床评价】

- 1010 加拿大急性呼吸道疾病和流感量表中文版在儿童普通
感冒中的最小临床重要差异值研究
郭圣璇, 胡思源, 光军秀, 蔡秋晗, 李井锋,
裴立超, 张 琦, 李瑞本

药物评价研究

YAOWU PINGJIA YANJIU
第44卷 第5期 2021年5月
(月刊)
1978年创刊

《药物评价研究》杂志第六届编辑委员会

名誉主编 桑国卫

主编 王广基

副主编 (按拼音为序)

丁 健 李 波 刘 耀

黄璐琦 杨宝峰 周宏灏

甄永苏 王军志 汤立达

陈常青 司端运

委员 (按姓氏拼音为序)

白 钢 曹 彩 岑小波 陈地龙

陈卫东 邱多隆 董江萍 杜晓曦

范 益 高秀梅 郭 青 何光杰

何 新 何 毅 侯文彬 洪丽萍

胡 蓓 胡思源 黄 民 黄芝瑛

季宇彬 贾英杰 姜德建 江立新

蒋学华 李 川 李春如 梁文波

廖明阳 刘岱琳 刘建忠 刘可春

刘克辛 刘晓东 娄建石 鲁 明

罗国安 罗晓健 吕 媛 马 璟

马双成 任晓文 沈竞康 沈晓红

沈志滨 宋海峰 宋新波 唐 星

王春龙 王 捷 王 睿 王伟民

王 怡 王玉芹 王峥涛 吴春福

吴 迪 吴青业 徐为人 杨海森

杨静玉 杨祥良 伊秀林 元唯安

赵 玲 张兰珍 张 力 张秀娟

张艳军 张彦文 张振清 张志荣

张宗鹏 周 芳 周建平 朱五福

编辑部主任 刘东博

编辑部成员 兰新新 李红珠 高 源

1016 寒喘祖帕颗粒联合孟鲁司特钠治疗儿童咳嗽变异性哮喘的疗效及其对气道炎症水平、免疫球蛋白及白三烯水平的影响
王 亮, 韩 娜, 刘宏伟, 史月静, 包淑迎

1022 心悦胶囊联合比索洛尔治疗冠心病心绞痛的疗效及其对血液流变学的影响 王银庄, 张继东, 徐凯丽

1027 替格瑞洛联合阿托伐他汀和阿司匹林对急性ST段抬高型心肌梗死PCI术后心肌血流灌注的影响
高建凯, 杨 平, 梁亚州, 张明礼

1033 莫家清宁丸治疗实热内结型不完全性肠梗阻的疗效观察及其对血清VIP、CRP、MTL水平的影响
李腾飞, 刘国顺

1037 慈航胶囊联合桂枝茯苓胶囊治疗产后恶露不尽的疗效观察
吕建利, 王占伟

1041 尼麦角林联合加兰他敏治疗老年卒中后认知障碍的疗效及其对血清SOD、MDA、NSE水平的影响
刘 瑞, 张潇潇, 赵 静, 孟会红, 刘永刚

1047 丹灯通脑胶囊联合丁苯酞治疗急性脑梗死的临床研究
李尽义, 贾东佩, 徐明超, 吴红举, 白方会

1053 膜香四黄颗粒联合阿替普酶治疗痰热腑型急性脑梗死的临床研究
刘 涛, 赵 欣

1060 复方脑肽节苷脂联合依达拉奉治疗急性脑梗死的疗效及其对血清S100 β 、NSE、8-iso-PGF_{2 α} 和MDA水平的影响
翟明明, 邹俊杰, 李昭盈

1066 坤宁颗粒联合米非司酮治疗围绝经期功能性子宫出血的临床研究
杨胜华, 杨 君

1071 坤泰胶囊联合米非司酮治疗子宫肌瘤的疗效分析
张爱凤, 刘卓勋, 张 倩, 李娟娟, 刘 玲, 张 红

【循证研究】

1076 茜参益气滴丸辨证施治对慢性心力衰竭疗效影响的Meta分析
牛振超, 林文勇, 李益萍, 强婷婷, 王肖龙

1088 阿托伐他汀对比瑞舒伐他汀对PCI术后远期心功能及不良心血管事件影响的Meta分析
杜高波, 贾小凤, 余 强, 李晓鹃

【综述】

1097 药物性肝损伤的肝细胞死亡方式及治疗药物研究进展
朱 英, 江振洲, 张陆勇

1105 莱菔硫烷调节脂肪肝的药理作用研究进展
赵佳鹤, 马欣雨, 徐敬娅, 段婷婷, 张春蕾, 李宝龙

1111 丙戊酸治疗药物监测研究进展
彭清萍, 宋沧桑, 李兴德, 张 阳, 张函舒

1117 金线莲多糖的药理作用及其机制研究进展
俞晓玲, 姜文倩, 游 晨, 叶寒辉

1122 氧化苦参碱心脏保护作用的研究进展 张明发, 沈雅琴

DRUG EVALUATION RESEARCH

Vol. 44 No. 5, May 2021

(Monthly)

Honorary Editor-in-Chief

SANG Guowei

Editor-in-chief

WANG Guangji

Associate Editors-in-chief

DING Jian	LI Bo
LIU Yao	HUANG Luqi
YANG Baofeng	ZHOU Honghao
ZHEN Yongsu	WANG Junzhi
TANG Lida	CHEN Changqing
SI Duanyun	

Directed by

Tianjin Institute of Pharmaceutical Research
(www.tjipr.com)

Sponsored by

Tianjin Institute of Pharmaceutical Research
(www.tjipr.com)
Chinese Pharmaceutical Association
(www.cpa.org.cn)

Edited and Published by

Editorial Office of Drug Evaluation Research
Address:306#Huiren Road, Binhai District,
Tianjin 300462, China
Tel / Fax: +86 22 2300 6822
URL: www.tiprpress.com
E-mail: der@tiprpress.com

Printed by

Tianjin Hengyuan Printing Co., Ltd.

Distribution

Self-Distribution

Standard Number

ISSN 1674-6376

CN 12-1409/R

Publication Date

May 8, 2021

Editor in Charge of This Issue

LI Hongzhu

Contents

- 909 Application of ePRO assessing efficacy in clinical trials of new drugs
LI Xiaoxian, ZHAO Ye, LIN Feng, ZHANG Zizhen, YUAN Weian
- 918 Expert consensus on information system management of investigational product(s)
CAI Junlong, ZHOU Jingjing, LI Xiaohui, HU Yongfang, MA Liping, LIU Qiao, WANG Shaohua, XIAO Sheng, ZHU Li, LI Haijun, LIN Mei, JI Xiaohui, ZHU Xueqi, WANG Jiaqing, WANG Shu, LI Jing, DIAO Li, GUO Shanshan, HUANG Wenjing, YANG Haimiao, QU Xinyao, QIU Yan, SUN Mengqi, WANG Shurong, BUGela·MIjiti, LIU Chunli, LIN Yang, LIU Lijun, DING Qian, LIU Zhen, HU Junyu, NIE Mingxing, ZHU Lusha, RONG Yingci, TANG Lei, WANG Jiao, ZHANG Yiwei, LIANG Xin, ZHANG Yi, AI Junbo, CHEN Zhou, CAO Wenzhong, XIE Chaoqing, CAO Cai, HUANG Jianying
- 924 Key points of research on quality control of related substances in single component drugs
SUN Yu, ZHENG Rui, WEN Hairuo
- 931 Introduction to EMA's simplified requirements of package leaflets and labels for COVID-19 vaccines and therapeutics
XIAO Huilai
- 936 Exploration on mechanisms of Simiao Yong'an Decoction in treating digital gangrene, diabetes and coronary heart disease with concept of "treating different diseases with same method" based on network pharmacology
LI Juan, ZHANG Yuejian, LI Tengteng, WANG Raoying, ZHANG Yuanfeng, WANG Xiting, LU Tao
- 949 Effect of Xiangsha Pingwei Keli on gastrointestinal function in rats with syndrome of damp retention in middle-jiao
LI Han, GAO Yunhang, SONG Ling, CHEN Tengfei, HOU Hongping, HUO Wang, ZHANG Guangping
- 956 Quality control of Huangzhi Yishen Capsules based on HPLC fingerprint combined with chemical pattern recognition
XUE Qimei, SHI Haiwei, QIAN Yefei, TAN Li, GUO Qing, MIN Chunyan,
- 964 Toxicokinetics and toxicity study of Levofloxacin Hydrochloride Injection administered intravenously in Beagle dogs
ZHANG Na, FANG Cheng, LIU Yongwu, PIAO Chengyu, DONG Wanru, AN Baisong, WU Xiuhong
- 971 Experimental study of hyperoside on process of atherosclerosis by regulating vascular endothelium via NOS/NO system
LIU Chi, MIN Dongyu, ZHU Jinghe, YUAN Yu, GUAN Xiaojiao, HU Liping
- 978 Pharmacodynamic evaluation of Zhike Chuanbei Pipa Dropping Pills for expectorant and antitussive and its effect on expression of MUC5AC in lung
LI Xueli, HAN Xu, WANG Jinlei, ZHUANG Pengwei, GUO Hong
- 984 Therapeutic effect of water extract of *Apocynum venetum* leaves on STZ induced diabetic mice and its effect on intestinal GLP-1 protein expression
HUANG Jingfeng, WANG Li, HE Wei, LIU Lei, LIU Xiaoyu, MA Fuchang, MA Li, LI Zhijian
- 990 Preparation of liposome Gel of *Carex meyeriana* Total Flavonoid
SU Ting, ZHAO Yan, BI Ye, GAO Lingyu, JIA Ruixin, BAO Zheng, LI He, QIU Zhidong
- 997 Experimental study on protective effect of Jiawei Shengmai San on acute kidney injury in rats with septic
WANG Shuai, WAN Xiaogang, QIU Chaobing, YI Zhibiao, WU Yonggang, CHEN Renshan, YAO Haihun, XIAO Caihong, LI Zehua
- 1004 GP73 regulates oxaliplatin resistance through EMT in hepatocellular carcinoma
LIU Xiaodong, WU Xiaomeng, WANG Dong, KANG Le, ZHANG Qi

DRUG EVALUATION RESEARCH

Vol. 44 No. 5, May 2021

(Monthly)

Editorial Committee

of *Drug Evaluation Research*

Honorary Editor-in-Chief

SANG Guowei

Editor-in-chief

WANG Guangji

Associate Editors-in-chief

DING Jian	LI Bo
LIU Yao	HUANG Luqi
YANG Baofeng	ZHOU Honghao
ZHEN Yongsu	WANG Junzhi
TANG Lida	CHEN Changqing
SI Duanyun	

Members of Editorial Board

BAI Gang	CAO Cai
CEN Xiaobo	CHEN Dilong
CHEN Weidong	DI Duolong
DONG Jiangping	DU Xiaoxi
FAN Yi	GAO Xiumei
GUO Qing	HE Guangjie
HE Xin	HE Yi
HOU Wenbin	HONG Liping
HU Bei	HU Siyuan
HUANG Min	HUANG Zhiying
JI Yubin	JIA Yingjie
JIANG DeJian	JIANG Lixin
JIANG Xuehua	LI Chuan
LI Chunru	LIANG Wenbo
LIAO Mingyang	LIU Dailin
LIU Jianzhong	LIU Kechun
LIU Kexin	LIU Xiaodong
LOU Jianshi	LU Ming
LUO Guoan	LUO Xiaoqian
LV Yuan	MA Jing
MA Shuangcheng	REN Xiaowen
SHEN Jingkang	SHEN Xiaohong
SHEN Zhibin	SONG Haifeng
SONG Xinbo	TANG Xing
WANGChunlong	WANG Jie
WANG Rui	WANG Weimin
WANG Yi	WANG Yuqin
WANG Zhengtao	WU Chunfu
WU Di	WU Qingye
XU Weiren	YANG Haimiao
YANG Jingyu	YANG Xiangliang
YI Xiulin	YUAN Weian
ZHANGLanzhen	ZHANG Li
ZHANG Xiujuan	ZHANG Yanjun
ZHANG Yanwen	ZHANG Zhenqing
ZHANG Zhirong	ZHANG Zongpeng
ZHAO Ling	ZHOU Fang
ZHOU Jianping	ZHU Wufu

- 1010 Minimal clinically important difference of Canadian Acute Respiratory Illness and Flu Scale Chinese version in children with common cold
GUO Shengxuan, HU Siyuan, GUANG Junxiu, CAI Qiuhan, LI Jingfeng, PEI Lichao, ZHANG Qi, LI Ruiben
- 1016 Effect of Hanchuan Zupa Granules combined with montelukast sodium in treatment of cough variant asthma in children and its effect on airway inflammation, immunoglobulin, and leukotriene levels
WANG Liang, HAN Na, LIU Hongwei, SHI Yuejing, BAO Shuying
- 1022 Effect of Xinyue Capsules combined with bisoprolol in treatment of angina pectoris of coronary heart disease and its effect on hemorheology
WANG Yinzhuan, ZHANG Jidong, XU Kaili
- 1027 Effect of ticagrelor combined with atorvastatin and aspirin on myocardial perfusion after PCI in acute ST-segment elevation myocardial infarction
GAO Jiankai, YANG Ping, LIANG Yazhou, ZHANG Mingli
- 1033 Effect of Mojia Qingning Pills in treatment of incomplete intestinal obstruction of excess-heat accumulation type and its effect on serum VIP, CRP and MTL levels
LI Tengfei, LIU Guoshun
- 1037 Clinical observation of Cihang Capsules combined with Guizhi Fuling Capsules in treatment of postpartum lochia endless
LÜ Jianli, WANG Zhanwei
- 1041 Effect of nicergoline combined with galanthamine in treatment of senile cognitive impairment after stroke and its effect on serum SOD, MDA and NSE levels
LIU Lu, ZHANG Xiaoxiao, ZHAO Jing, MENG Huihong, LIU Yonggang
- 1047 Clinical study of Dandeng Tongnao Capsules combined with butylphthalide in treatment of acute cerebral infarction
LI Jinyi, JIA Dongpei, XU Mingchao, WU Hongju, BAI Fanghui
- 1053 Clinical study of Shexiang Sihuang Granules combined with alteplase in treatment of phlegm-heat abdominal solid type acute cerebral infarction
LIU Tao, ZHAO Xin
- 1060 Effect of compound porcine cerebroside and ganglioside combined with edaravone in treatment of acute cerebral infarction and its effect on serum S100 β , NSE, 8-iso-PGF_{2 α} and MDA levels
Zhai Mingming, ZOU Junjie, LI Zhaoying
- 1066 Clinical study of Kunning Granules combined with mifepristone in treatment of perimenopausal functional uterine bleeding
YANG Shenghua, YANG Jun
- 1071 Efficacy of Kuntai Capsules combined with mifepristone in treatment of uterine fibroids
ZHANG Aifeng, LIU Zhuoxun, ZHANG Qian, LI Juanjuan, LIU Ling, ZHANG Hong
- 1076 Meta-analysis of clinical effects according to syndrome differentiation of Qishen Yiqi Dropping Pills on chronic heart failure
NIU Zhenchao, LIN Wenyong, LI Yiping, QIANG Tingting, WANG Xiaolong
- 1088 Meta-analysis of effect of atorvastatin vs rosuvastatin on long-term cardiac function and major adverse cardiac events (MACE) after percutaneous coronary intervention (PCI)
DU Gaobo, JIA Xiaofeng, YU Qiang, LI Xiaojuan
- 1097 Research advances of hepatocyte death and therapeutic drugs in drug-induced liver injury
ZHU Ying, JIANG Zhenzhou, ZHANG Luyong
- 1105 Research progress on pharmacological effects of sulforaphane in regulating fatty liver disease
ZHAO Jiahe, MA Xinyu, XU Jingya, DUAN Tingting, ZHANG Chunlei, LI Baolong
- 1111 Research progress of valproic acid therapy drug monitoring
PENG Qingping, SONG Cangsang, LI Xingde, ZHANG Yang, ZHANG Hanshu
- 1117 Research progress on pharmacological action and mechanism of polysaccharides from *Anoectochilus roxburghii*
YU Xiaoling, JIANG Wenqian, YOU Chen, YE Hanhui
- 1122 Research advances on cardioprotective effect of oxymatrine
ZHANG Mingfa, SHEN Yaqin