Saint Petersburg State Budget Establishment of Health Care City Hospital No 40

HIGH TECHNOLOGY METHODS OF TREATMENT AND REHABILITATION

THEORY AND PRACTICE

YEARBOOK 2012

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Doctor of Medical Sciences
Professor *S. G. Scherbak*

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Reviewer:
Honoured Scientist of the Russian Federation prof. P.N. Zubarev (Saint Petersburg)

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The current edition is a collection of works on theory and practice performed by physicians of the City Hospital No 40, Saint Petersburg, Russia, in 2012. This is already the third yearbook. The book's peculiarity is a broad collaboration of representatives of other scientific and medical establishments of Saint Petersburg. The book consists of eleven chapters. The first chapter presents an attempt to analyze evolution of the legal aspects of medical research regulation. The authors see the way to overcome the crisis in which the domestic medical science is currently involved in return to the basic principles of Declaration of Helsinki with implementation of the modern international standard of medical investigations – CONSORT 2010. The following three chapters cover the practical implementation of the second chapter guidelines. Specifically, chapter 2 comprises the clinical investigation plan of estimation of the long term effectiveness of cardiac shock wave therapy in the general system of ischemic heart disease treatment, chapter 3 – the package of five documents regulated this clinical investigation conduction. Chapter 4 generalizes the experience of such a project conduction. Chapter 5 is a review of methodological problems of submillimeter (terahertz) biological action radiation research. Taking as an example one of domestic doctor thesis, the basic methodological faults in the field are demonstrated. Then an outline of a correct design of the experiment

in vitro is presented. Chapter 6 possesses a draft of a clinical trial plan for effectiveness of terahertz and chromotherapy separately or combined with acupuncture in various etiology coma treatment resistant to standard methods evaluation. The chapter 7 for the first time in our yearbooks deals with the surgical theme. It is dedicated to evolution and the current state of the problem of total hip arthroplasty with minimally invasive antero-lateral approach. Chapter 8 presents the current state and prospects of health status monitoring of the USA population and Armed Forces personnel. It is convincingly showed the role of reliable information in the major healthcare decision making. Chapter 9 considers the modern ideas in the field of mechanisms of action of some plants traditionally employed in sexual dysfunctions treatment. The obvious primitivism of the existing synthetic drugs for sexual dysfunction treatment which in essence is merely symptomatic is demonstrated. Hence the natural alternative of such a treatment appears to be phytotherapy which has been employed from time immemorial for sexual dysfunction restoration and improvement. Chapter 10 analyzes the modern point of view on the pathogenesis of traumatic brain injury, a combat as well as sport. It is shown the increasing importance of this kind of pathology for civilian and military medicine. The last, eleventh chapter, comprises a sketch on the topic of our hospital development against a broader background of the city of Sestroretsk healthcare development. The chapter abstracts in Russian and English are situated before the corresponding chapters. Bibliography is at the end of each chapter. The collection is completed by the index of basic terms contained in the text.

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CONTENTS

ABSTRACTS OF INDIVIDUAL CHAPTERS

Chapter 1

EVOLUTION OF PRINCIPLES OF THE LEGAL ASPECTS OF MEDICAL RESEARCH REGULATION

A SEMANTIC ANALYSIS EXPERIENCE

Scherbak S.G., Golota A.S., Anisenkova A.Yu., Belokopytov I.Yu., Il'in D.A., Krassii A.B., Lisovets D.G., Makarenko S.V., Makar'ina E.S., Sarana A.M., Usikova E.V.

The current chapter is dedicated to semantic analysis of evolution of the legal aspects of medical research regulation. It is shown that before the mid-40s of the past, 20th century, the scientific research in the field of medicine had been conducted on the basis of universal and corporate ethics like *Hippocratic Oath*. However, the monstrous experiments performed on people and made public to the international community had urgently required introduction of legal regulation into the sphere of medical research. The first document of such a kind was the *Nuremberg Code* then developed

into the *Declaration of Helsinki* (DoH) «Ethical Principles for Medical Research Involving Human Subjects» in which for the first time the most effective tool against abuse of any kind, namely: publicity, had been applied. For that purpose the DoH provided two procedures: (1)research protocol registration at a publicly available data base *before* beginning of the first patient enrolment (art. 19) and (2)mandatory publication of all research results including negative and undefined (art. 30). To the mid-90s of the 20th century by the effort of influential international pharmaceutical business lobbyists, the DoH principles had been factually eliminated and substituted by *Good Clinical Practice* standards. The ubiquitous character of scientific results falsification and fabrication with massive plagiarism have led to the situation when works of domestic authors are practically not published in the leading foreign scientific journals which means that we stop participating in the international process of knowledge acquisition and exchange. Even the leaders of the Russian Academy of Science have been compelled to estimate the state of the domestic science as disastrous. An escape from the existing situation, particularly, in medical sciences is seen in return to the basic principles of DoH with implementation of the CONSORT 2010 tools.

Key words: bioethics, clinical research, clinical trial, CONSORT 2010, Helsinki Declaration, medical ethics, medical research, semantics, thesaurus.
MeSH terms: Bioethics, Biomedical Research, Clinical Trial, Ethics Medical, Helsinki Declaration, Semantics, Vocabulary Controlled.
UDC: 614.2+617.8+81’31
Bibliography: 41 items.

Chapter 2

ESTIMATION OF THE LONG TERM EFFECTIVENESS OF ROUTINE USE OF CARDIAC SHOCK WAVE THERAPY IN THE GENERAL SYSTEM OF NONINVASIVE, INVASIVE, AND SURGICAL TREATMENT OF ISCHEMIC HEART DISEASE IN THE CONDITIONS OF A LARGE GENERAL CITY HOSPITAL

A CLINICAL INVESTIGATION PLAN

Golota A S., Lisovets D.G., Agaf'ina A.S., Dolhonova T.V., Zelenina L.I., Krassii A.B., Larin K.E., Lebedeva S.V., Noskov A.V., Popov A.E., Razorenova T.S.

Introduction to the theme. Russia leads the world in coronary heart disease (CHD) mortality leaving behind other countries multiply and some of them by the power of ten. One of the causes of such a situation is standard CHD treatment inefficiency. In this connection it is understandable the heightened interest to the second line methods of CHD treatment. One of those methods is cardiac shock wave therapy (CSWT). The method is 14 years old. About a score of various studies have been dedicated to it *in vivo* as well clinical trials up to phase III. The grand total: (1)the method is practically safe and well tolerated, (2)the intervention according to clinical and instrumental observations is significantly effective. Meanwhile, it has been unclear: (1)how long CSWT provided remission lasts, so far all investigations are limited to one year, (2)if CSWT influences such basic health quality improvement indicators as, e.g., life span, (3)a place of CSWT in the general system of conservative and surgical CHD treatment and also a long-term effect of combined employment of the method with invasive modalities.

Aim and goals. To ascertain the long term effectiveness of routine use of CSWT in the general system of noninvasive, invasive, and surgical CHD treatment. For that purpose to estimate the CSWT influence on such basic health quality improvement indicators as life span increase, reduction of major cardiovascular events number, to find out the length of remission

obtained with the help of CSWT employment. The project is planned in strict accordance with the modern international standards of nonpharmacological clinical investigations CONSORT 2010 and STRICTA 2010 to provide the possibility of the present research materials publication at the leading foreign scientific medical journals, as well as in correspondence with regulations of the effective domestic nonpharmacological clinical research standard GOST 14155–2008.

Material and methods. Design: observational, prospective. For that purpose the seven cohorts are formed: (1)the patients without CHD or with class 0 angina according to the Canadian Cardiovascular Society Angina Classification, (2)patients with class 1 angina, (3)patients with class 2–4 angina receiving only maximal antianginal medical therapy for whom it is effective, (4)the patients undergone percutaneous coronary angioplasty, (5)the patients after coronary artery bypass grafting, (6)the patients received CSWT, (7)the patients with class 2–4 angina receiving only maximal antianginal medical therapy for whom it is not effective or not sufficiently effective, although for some reasons they have not received any other interventions. The expected number of participants 2–3 thousand. Primary end points: (1)outcome – death (lethality), (2)major cardiovascular complications. Secondary end points: (1)the number of hospitalizations for the period of observation, (2)the number of hospitalization days for the period of observation. Follow-up stages (6 altogether): the moment of inclusion and annual check-up for five years. Taking into consideration a three-year enrollment period, the total length of the project is 8 years.

Expected results and discussion of them: the present investigation is the first long term observational prospective study of CSWT effectiveness that inevitably lends it a pilot quality. Regardless of the bringing forward null

hypothesis accepting or its rejecting for the benefit of the alternative one, the present project will serve as an impetus for starting up a series of multicenter international investigations. And this is an underlying objective of the clinical researchers team.

Key words: clinical investigation plan, clinical research, coronary heart disease, cardiac shock wave therapy, myocardial revascularization, observational research, prospective research.
MESH terms: Biomedical Research, Coronary Disease, Myocardial Revascularization.
UDC: (616.1:616-08: 615.4) 617-07
Bibliography: 42 items.

Chapter 3

A PACKAGE OF AUXILIARY DOCUMENTS WHICH REGULATE THE CONDUCTION OF THE CLINICAL INVESTIGATION

Golota A S., Lisovets D.G., Agaf'ina A.S., Dolhonova T.V., Zelenina L.I., Krassii A.B., Larin K.E., Lebedeva S.V., Noskov A.V., Popov A.E., Razorenova T.S.

The current chapter comprises five mandatory documents regulated clinical investigation conduction and supplemented the Clinical investigation plan which has been presented in the previous chapter, notably, (1)Information for the subject, (2)Informed consent form, (3)Investigator's brochure, (4) Case report form, (5)Agreement between the sponsor and the investigation team. The presence and structure of all above motioned documents are regulated by GOST R ISO 14155–2008.

Key words: agreement between the sponsor and the investigation team, case report form, coronary heart disease, cardiac shock wave therapy, clinical research, information for the subject, informed consent form, investigator's brochure, myocardial revascularization, observational research, prospective research.
MESH terms: Biomedical Research, Coronary Disease, Informed Consent, Myocardial Revascularization.
UDC: (616.1:616-08: 615.4) 617-07
Bibliography: 3 items.

Chapter 4

THE EXPERIENCE OF ORGANIZATION OF A CLINICAL INVESTIGATION IN THE NEW INTERNATIONAL FORMAT

Golota A S., Lisovets D.G., Agaf'ina A.S., Dolhonova T.V., Zelenina L.I., Krassii A.B., Larin K.E., Lebedeva S.V., Noskov A.V., Popov A.E., Razorenova T.S.

This article reflects the experience of organization of an international class clinical investigation in the new international format CONSORT 2010, STROBE. The project is dedicated to study of the long term effectiveness of cardiac shock wave therapy use in the general system of noninvasive, invasive, and surgical treatment of ischemic heart disease in the conditions of a large general city hospital with the employment of prospective cohort observation method. The features of the new format are described, the management directives which regulate clinical investigations in that format are adduced, the resulting document package accompanying such a study is characterized, the basic phases of the project preparation process are noted, the necessity of protocol registration at an international registry as a mandatory prerequisite of the following results publication possibility in the leading international periodicals is emphasized.

Key words: clinical research, CONSORT 2010, coronary heart disease, cardiac shock wave therapy, Declaration of Helsinki, myocardial revascularization, observational research, prospective research, STROBE.
MeSH terms: Biomedical Research, Clinical Trial, Coronary Disease, Helsinki Declaration, Myocardial Revascularization.
UDC: 615.4:615:8: 616-08: 616.1
Bibliography: 23 items.

Chapter 5

STUDY OF BIOLOGICAL ACTION OF SUBMILLIMETER/TERAHERTZ RADIATION

A REVIEW OF METHODOLOGICAL PROBLEMS

***Veselova O.M.*[1], *Golota A.S.*, *Krassii A.B.*, *Murzina E.V.*[1], *Reukov A.S.*[2], *Snopov S.A*[3].**

This chapter focuses on the methodological problems arising in research of biological action of submillimeter/terahertz (subMM/TH) radiation. First, we give a short look on the metrology and nomenclature of electromagnetic waves. Second, we perform a critical analysis of some non-appropriate approaches applied in experimental studies of subMM/TH radiation effects on biologic objects. As an example of such an experimental study we analyze a Doctor thesis issued in Russia. Third, we offer a research project design for *in vitro* study of cellular effects of this radiation, in which we try to address the key requirements for such experiments to date.

Key words: biological effects, infrared radiation, non-drug medicine, photobiology, submillimeter radiation, terahertz radiation/
MeSH terms: Infrared Rays, Microwaves, Radiobiology, Terahertz Radiation.
UDC: (61:577.3+61:57.086) 615.84
Bibliography: 39 items.

[1] Military Medical Academy after S.M. Kirov, Saint Petersburg, Russia
[2] Almazov Federal Heart, Blood and Endocrinology Center, Saint Petersburg, Russia
[3] Institute of Cytology of the Russian Academy of Sciences, Saint Petersburg, Russia

Chapter 6

THE EFFECTIVENES OF TERAHERTZ AND CHROMOTHERAPY SEPARATELY OR COMBINED WITH ACUPUNCTURE IN VARIOUS ETIOLOGY COMA TREATMENT RESISTANT TO STANDARD METHODS

A CLINICAL TRIAL PLAN

(A SKETCH)

Golota A.S., Buznik G.V., Dokish Yu.M., Krassii A.B., Popov A.E., Razorenova T.S., Reukov A.S.*[1]*, Smantserev K.V., Usikova E.V.

Introduction to the theme. Some recently emerged reports have pointed out that selected non-pharmacological methods of treatment, in particular, infrared radiation with terahertz modulation and chromotherapy separately or combined with acupuncture are effective in various etiology coma treatment resistant to standard methods. In view of high medical social and scientific conceptual significance of the presented in those reports factual information, it is urgently necessitated the verification of the above mentioned methods inside the network of evidence-based medicine paradigm in the form of 0–I phase clinical trial.

Aim and goals: to find out whether the employment of the above mentioned physiotherapeutic modalities is actually effective in the resistant to standard treatment coma therapy. For that purpose to organize a randomized controlled clinical trial which should be planned in strict compliance with modern scientific standards of nonpharmacological type clinical trials conduction CONSORT 2010 and STRICTA 2010 in order to provide a possibility for trial results publication in leading foreign scientific medical periodicals.

Material and methods. Design: prospective, interventional, therapeutic, randomized, open, parallel, actively controlled, in phase 0–I.

[1] Almazov Federal Heart, Blood and Endocrinology Center, Saint Petersburg, Russia

Two comatose patient groups are created by randomization: (1)treated by the current international standards – a group of active control (cohort 0) and (2)treated by the current international standards + infrared radiation with terahertz modulation and chromotherapy separately or combined with acupuncture – experimental group (cohorts 1–6). An approximate number of patients is 150. The end points: the only primary end poin of the current investigation is an outcome resulted in death. The secondary end points: (1)development of life-threatening complications like stroke or myocardial infarction and (2)one of comprehensive patient functioning estimation methods, e.g. Barthel index. Follow-up stages (7 altogether): the moment of inclusion into the trial, 20^{th} to 30^{th} days, in 3, 6 months, in 1, 2 and 3 years.

Anticipated results and their discussion. The current trial is the first investigation of infrared radiation with terahertz modulation and chromotherapy separately or combined with acupuncture effectiveness in the patients with various etiology coma treatment resistant to standard methods. That inevitably brings the given trial a pilot nature. Depending on whether the zero hypothesis laid in this trial is accepted or rejected for the benefit of alternative one, the current project will serve as an impetus for development of other multicentral international trials at the same direction or will close the theme thus saving human and material resources for solving other problems in the field of comatose state treatment improvement.

Key words: acupuncture, clinical research, color therapy, clinical trial, hypoxic coma, infrared radiation, prospective research, stroke, terahertz radiation.
MeSH terms: Acupuncture, Biomedical Research, Brain Ischemia, Color Therapy, Coma, Stroke, Terahertz Radiation, Therapeutics.
UDC: (616.8+615.8) 616.08:617-07
Bibliography: 18 items.

Chapter 7

TOTAL HIP ARTHROPLASTY (THA) WITH MINIMALLY INVASIVE ANTERO-LATERAL APPROACH

EVOLUTION OF THE CONCEPTION AND THE CURRENT STATE OF THE PROBLEM

Andreev D.V.*[1]*, Golota A.S., Krassii A.B., Mariutin P.V., Nikitin A.V., Shuginov A.A.

The present review is dedicated to the current state of total hip arthroplasty (THA) with minimally invasive antero-lateral approach problem. The review begins with analysis of the literature search on the theme followed by bibliometrics. Then the basic landmarks of the THA method are briefly characterized and the latest international statistics data are presented. Because of THA technique rapid development, the following section with the already obtained clinical trials results on the theme is based on 2010–2011 publications. After it the current clinical trials are characterized in detail.

Key words: arthroplasty, hip, hip prosthesis, total hip replacement.
MeSH terms: Arthroplasty; Hip Prosthesis; Replacement, Hip.
UDC: 616.3:617.7
Bibliography: 105 items.

Chapter 8

HEALTH STATUS MONITORING OF THE USA POPULATION AND ARMED FORCES PERSONNEL

THE CURRENT STATE AND PROSPECTS

REVIEW OF FOREIGN WEB-PUBLICATIONS

Rezvantsev M.V*[2]*, Golota A.S., Dokish Yu.M., Krassii A.B., Petrov S.V.*[2]*, Popov A.E.

The current review covers the modern state and development prospects of health status monitoring of the USA population and Armed Forces personnel. At the beginning as an introduction to the theme, it is considered

[1] Traumatology & Orthopedics Scientific Research Institute after R.R. Vreden, Saint Petersburg, Russia
[2] Military Medical Academy after S.M. Kirov, Saint Petersburg, Russia

the modern approaches to definition of the term «health» and its content structure including *World Health Organization's International Classification of Disability, Functioning and Health*. Besides, it is presented the notion of distinctive features of the American medical statistics which substantially differs from our domestic one. Then the organizations for health status monitoring are introduced. The governmental structures are shown in more detail. The private and public organizations are demonstrated in typical examples. A separate part of the review is dedicated to more thorough description of medical statistics publications. From numerous serial publications it has been selected two: (1) a statistical yearbook of the US Department of Health & Human Services *Health, United States* and (2)US Department of Defense *Medical Surveillance Monthly Report*. The next section analyzes health status monitoring methods from which are singled out three: (1)representative sample, (2)the entire population survey, (3)observational cohort study. The last review section is dealt with the prospects of health status monitoring progress. As a «future model» it is presented already employed the US Department of Defense *Theater Medical Information Program*. It is supposed that this project will include not only the battle field but the garrisons as well and then gradually expand to the entire national health care system.

Key words: *Armed Forces Health Surveillance Center*, birth rate, control automation, cybernetics, health, health status indicators, health survey, *Health, United States*, hospitalization, mass screening, *Medical Surveillance Monthly Report*, military medicine, morbidity, *Morbidity and Mortality Weekly Report*, mortality, *National Center for Health Statistics*, office visits, population surveillance, *Theater Medical Information Program*, USA, vital statistics.

MeSH terms: Automation, Cybernetics, Health, Health Status Indicators, Health Surveys, Hospitalization, Mass Screening, Medical Informatics, Military Medicine, Morbidity, Mortality, Office Visits, Population Surveillance, United States, Vital Statistics.

UDC: (004+681.5)355.41:355.0(73-41)

Bibliography: 138 items.

Chapter 9

THE MODERN CONCEPTIONS OF MECHANISM OF ACTION OF SOME PLANTS TRADITIONALLY EMPLOYED IN SEXUAL DYSFUNCTIONS TREATMENT

REVIEW OF FOREIGN WEB-PUBLICATIONS

Scherbak S.G., Barnaulova S.O., Golota A.S., Krassii A.B., Popov A.E., Sarana A.M.

The current review is dedicated to one of quite actual aspects of medicine – sexual dysfunctions treatment by means of medicinal plants with special focus on the modern conceptions of their mechanism of action. The review itself is preceded by introduction to the theme demonstrated the male and female sexual dysfunctions prevalance range attributed to the so called sexual revolition. It is noted sparse synthetic medications for sexual dysfunction treatment appearing on the pharmaceutical market nowadays. The current views on physiology of human sexual behavior are briefly characterized. In this context it is underlined that the normal sexual life is a whole brain function and requires the coordinated work of its many parts. Males and females possess substantial differencies which are somewhat genetically determined. In connection with that, it is ascertained the obvious primitivism of the existing synthetic drugs for sexual dysfunction treatment which in essence appears as merely symptomatic. The natural altermative of such a treatment may be phytotherapy which has been employed from time immemorial for sexual dysfunction restoration and improvemen. The rewiew itself comprises mechanism of action description of the first ten items from one of numerous and intersecting web lists of plants traditionally employed for sexual dysfunctions treatment in various ethnocultures. For pharmacodynamical characteristics it has been selected the 2011–2012

scientific medical publications carried out at the modern level with the newest molecular biology analytical methods employment. This review has been considered as an indroduction to a monograph on the modern phytotherapy of sexual disfunctions.

Key words: pharmacodynamics, phytotherapy, sexual dysfunction, treatment.
MESH terms: Phytotherapy; Sexual Dysfunction.

Chapter 10

PATHOGENESIS OF COMBAT AND SPORT TRAUMATIC BRAIN INJURY

THE CURRENT STATE OF THE PROBLEM

REVIEW OF 2011–2012 FOREIGN WEB-PUBLICATIONS

Ivchenko E.V.*[1], *Volodina S.T.*, *Gaidash A.A.*[1], *Kornilova A.A.*[2], *Krassii A.B.*, *Popov A.E.*, *Rezvantsev M.V.*[1], *Spirin A.B.

The current review is dedicated to one of the most urgent topic of the modern foreign military medicine, and especially US military medicine, the problem of traumatic brain injury (TBI). This diagnosis has become a kind of US Afghanistan and Iraq military campaign combat injury signature. The review is preceded by introduction to the theme with concise and instructive background. Then the information on TBI statistics, biophysics, molecular biology and neuroimiging is presented on the basis of 2011–2012 publications. Common and different features of blast and «civilian», and particularly sports, TBI pathogenesis are considered. On the basis of the whole set of available information it is suggested that the possible explosive TBI mechanism involves the chest elastic properties limitation due to permanent restrictive body armor impact or its anti-thixotropic quality appeared at the moment of explosion.

Key words: anti-thixotropy, apolipoprotein E4, armed forces, beta-amyloid, blast injury to brain, Center for neuroscience and regenerative medicine, chronic traumatic

[1] Military Medical Academy after S.M. Kirov, Saint Petersburg, Russia
[2] Rostov State Medical University, Rostov-on-Don, Russia

encephalopathy, Defense and veterans brain injury center, diffuse axonal injury, glial fibrillary acidic protein, improvised explosive device, integrins, interceptor body armor, medical service, military medicine, posttraumatic stress disorder, sports medicine, stathmin 1, tau protein, thixotropy, traumatic brain injury, ubiquitin carboxyl-terminal hydrolase isozyme L1.
MESH terms: Amyloid beta-Peptides; Apolipoprotein E4; Brain Injuries; Glial Fibrillary Acidic Protein; Integrins; Military Medicine; Sports Medicine; tau Proteins; Stathmin; Ubiquitin carboxyl-Terminal Hydrolase L-1, human.
UDC: (612.81+616.001)616-012
Bibliography: 99 items.

Chapter 11

ON THE TOPIC OF THE HISTORY OF SESTRORETSK MEDICAL ESTABLISHMENTS

Scherbak S.G., Dokish Yu.M., Zhuravlev D.A.

The current essay is a history of the City hospital No 40 of Saint Petersburg presented against a broader background of the city of Sestroretsk healthcare system development from 1748 to the present time.

Key words: City hospital No 40 of Saint Petersburg, history of medecine, Sestroretsk.
MeSH terms: History of Medicine.
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Bibliography: 12 items.