How NOT to write a manuscript that cannot be published

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Mechanical lung ventilation
Medical technology
Physical Chemistry

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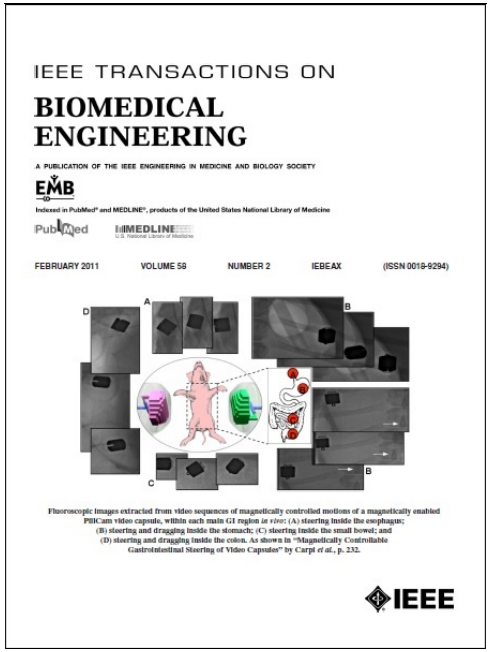
Motivation & problem

Before I start...

Level & quality = *f* (responsibility)
Medical *vs.* other journals
Clinical trials



Motivation & problem

Before I start...

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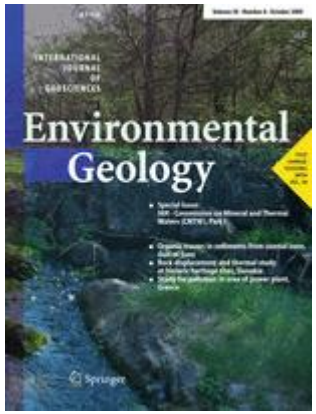
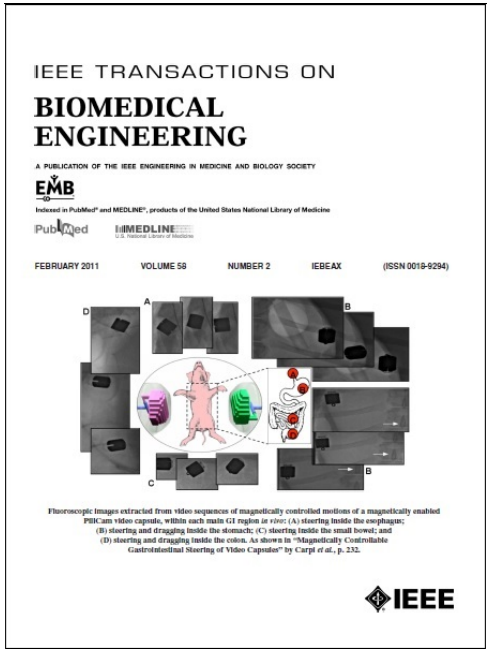
Clinical trials





Motivation & problem

Requirements of the journal before publication of the following article in PlosOne:

Roubík K, Sieger L, Sykora K (2015)

Work of Breathing into Snow in the Presence versus Absence of an Artificial Air Pocket Affects Hypoxia and Hypercapnia of a Victim Covered with Avalanche Snow: A Randomized Double Blind Crossover Study.

PLoS ONE 10(12): e0144332.

We consider your study to be a clinical trial, following the WHO definition: "**A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.**" Please see http://www.plosone.org/static/editorial#clinical for our policies on clinical trials.

PLOS ONE requires that all clinical trials are registered in an appropriate registry (the WHO list of approved registries is at http://www.who.int/ictrp/network/primary/en/index.html and more information on trial registration is at http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/).

Please give the name of the registry and the registration number (e.g. ISRCTN or ClinicalTrials.gov) in the submission data and on the title page of your manuscript.

If you have not registered your trial in an appropriate registry, we now require you to do so and will need confirmation of the trial registry number before we can pass your paper to the next stage of review. Please include in the Methods section of your paper your reasons for not registering this study before enrolment of participants started.

Please change your Article Type from “Research Article” to “Clinical Trial” when submitting your manuscript.

Please note that you must upload a completed CONSORT flowchart as figure 1 of your manuscript and the CONSORT checklist as a supporting information file. Blank copies of these documents and information regarding CONSORT can be found via the following link: http://www.consort-statement.org/. If your clinical trial uses a non-randomized design, you may wish to submit a TREND checklist (http://www.cdc.gov/trendstatement), in place of the CONSORT checklist; a flowchart is still required.”

Please upload a copy of your trial study protocol as a supporting information file. By the study protocol, we mean the complete and detailed plan for the conduct and analysis of the trial that the ethics committee approved before the trial began. Please send this in the original language. If this is in a language other than English, please also provide a translation. Please detail any deviations from this study protocol in the Methods section of your manuscript. Your study protocol will be made available to the editors and reviewers, and will be published as supporting information with your manuscript if accepted for publication. (*If you do not agree to this, we will not be able to publish your manuscript*). If you have formally published a study protocol for your trial in a journal then you should cite this in your manuscript, but you still need to send us the original document.

Czech journals – an example

Pokyny pro autory a recenzenty
časopisu **Anesteziologie a intenzivní medicína**

V souladu s Helsinskou deklarací a požadavkem ICMJE (International Commitee of Medical Journal Editors) musí být klinické intervenční studie, zařazující pacienty po 1. 1. 2015, registrovány v některé z existujících databází (např. ClinicalTrials.gov).

Parties involved

World Health Organization

International Clinical Trials Registry Platform (ICTRP)

WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

ClinicalTrials.gov

EU Clinical Trials Register

...

Final Rule for FDAAA 801 and NIH Policy on Clinical Trial Reporting

CONSORT TRANSPARENT REPORTING of TRIALS

Reporting guidelines:
CONSORT
STROBE
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ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals (ICMJE Recommendations)

WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964
and amended by the .... 64th WMA General Assembly, Fortaleza, Brazil, October 2013

The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

Research Registration and Publication and Dissemination of Results

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

http://www.wma.net/en/30publications/10policies/b3/

Parties involved

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ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

See the document:
http://www.icmje.org/about-icmje/faqs/icmje-recommendations/

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Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals

Updated December 2015

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Who Is an Author?

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; **AND**
2. Drafting the work or revising it critically for important intellectual content; **AND**
3. Final approval of the version to be published; **AND**
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work he or she has done, an **author should be able to identify which co-authors are responsible for specific other parts of the work**.

Those who do not meet all four criteria should be acknowledged—see Section II.A.3.

Predatory or Pseudo-Journals

A growing number of entities are advertising themselves as "scholarly medical journals" yet do not function as such. These journals ("**predatory**"or "**pseudo-journals**") accept and publish almost all submissions and charge article processing (or publication) fees, often informing authors about this after a paper's acceptance for publication. They often claim to perform peer review but do not and may purposefully **use names similar to well established journals**. They may state that they are members of ICMJE but are not (see www.icmje.org for current members of the ICMJE) and that they follow the recommendations of organizations such as the ICMJE, COPE and **WAME**. Researchers must be aware of the existence of such entities and avoid submitting research to them for publication. Authors have a responsibility to evaluate the integrity, history, practices and reputation of the journals to which they submit manuscripts. Guidance from various organizations is available to help identify the characteristics of reputable peer-reviewed journals (**http://www.wame.org/identifying-predatory-or-pseudo-journals**, ...).

Predatory publishers: https://beallslist.weebly.com/.

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Protection of Research Participants

All investigators should ensure that the planning conduct and reporting of human research are in accordance with the **Helsinki Declaration** as revised in...

All authors should seek approval to conduct research from an independent local, regional, or national review body (e.g., ethics committee, **institutional review board**)...

When reporting experiments on animals, authors should indicate whether institutional and national standards for the care and use of laboratory animals were followed. Further guidance on animal research ethics is available from the International Association of Veterinary Editors' Consensus Author Guidelines on Animal Ethics and Welfare (http://veteditors.org/ethicsconsensusguidelines.html).

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Interesting topics covered (examples):

- Copyright
- Overlapping Publications
- Duplicate and Prior Publication
- Acceptable Secondary Publication
- Manuscripts Based on the Same Database

Clinical Trials

Registration

The ICMJE requires, and recommends that all medical journal editors require, registration of clinical trials in a public trials registry at or before the time of first patient enrollment as a condition of consideration for publication.

The ICMJE accepts publicly accessible registration in any registry that is a primary register of the WHO International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/network/primary/en/index.html) or in ClinicalTrials.gov, which is a data provider to the WHO ICTRP.

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Preparing a Manuscript for Submission to a Medical Journal

Reporting Guidelines

Reporting guidelines have been developed for different study designs; examples include:

CONSORT for randomized trials (www.consort-statement.org),
STROBE for observational studies (http://strobe-statement.org/),
PRISMA for systematic reviews and meta-analyses (http://prisma-statement.org/),
STARD for studies of diagnostic accuracy (www.stard-statement.org/).

Manuscript Sections

Methods

The Methods section should include a statement indicating that the research was approved by an independent local, regional or national review body (e.g., ethics committee, institutional review board)...

Selection and Description of Participants

Technical Information

Statistics

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Preparing a Manuscript for Submission to a Medical Journal

Manuscript Sections

Discussion
It is useful to begin the discussion by briefly summarizing the main findings...

References

Preparation of the manuscript:

Illustrations
Figures
Tables
Units of Measurement
Abbreviations and Symbols
...

19
pages

Parties involved

World Health Organization

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Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals (ICMJE Recommendations)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 11

[Docket Number NIH-2011-0003]

RIN: 0925-AA55

Clinical Trials Registration and Results Information Submission

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Final Rule.

https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-22129.pdf

Clinical Trials Registration and Results Information Submission

National Institutes of Health, Department of Health and Human Services

See the document:
https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-22129.pdf

It requires that the responsible party register (in linicalTrials.gov.) an applicable clinical trial **not later than 21 calendar days after enrolling the first human subject**.

This rule requires **the submission of results information not later than 1 year after the completion date** (referred to as the "primary completion date") of the clinical trial, which is defined as the date of final data collection for the primary outcome measure. Results information submission could be delayed for up to 2 additional years...

This final rule requires that all submitted **information be updated** at least annually if there are changes to report. More rapid updating is required...

This final rule will be effective January 18, 2017.

ClinicalTrials.gov accepts information on trials other than those legally required to be registered in support of the mission of the NLM and other policies such as those from the ICMJE.

The information that describes the clinical trial in the registry records also facilitates assessments of the quality and appropriateness of trial reporting by enabling journal editors, researchers, and other readers of the medical literature to assess the degree to which the disclosed results (e.g., journal articles, scientific conferences) accurately reflect the prespecified protocol and have accounted for all prespecified outcome measures. This helps to (1) prevent the type of incomplete results reporting that has been documented in conference and journal abstracts, as well as in full journal articles [Ref. 33] and (2) allow the members of the public to assess fidelity to the protocol, which is essential to understanding the validity of disclosed results.

The **public availability of results** information **helps investigators design trials and IRBs review proposed trials**, by allowing them to weigh the proposed study's risks and benefits against a more complete evidence base than is currently available through the scientific literature. The rule facilitates better science through aiding in the identification of knowledge gaps for trials of all types of products, whether unapproved or approved and marketed. Mandatory submission and posting of results information will also help investigators ***avoid repeating trials*** on drug and device products (including biological products) that have been found to be unsafe or unsuccessful while also providing access to information that may help verify findings.

The submission and posting of results information on ClinicalTrials.gov may occur before, simultaneously with, or after journal publication, but is independent of journal submission and publication.

The legal requirements help to fill substantial gaps in the database left by the non-publication (or very delayed publication) of a substantial portion of clinical trials in the medical literature. ...

The availability of results information from applicable clinical trials will help to prevent skewing of the evidence base that is the foundation of systematic reviews and clinical practice guidelines.

“Clinical trial” in § 11.10(a) to mean “a clinical investigation or a clinical study in which human subjects are prospectively assigned, according to a protocol, to one or more interventions (or no intervention) to evaluate the effects of the interventions on biomedical or health-related outcomes.”

“Applicable device clinical trial” is a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the FD&C Act against a control in human subjects (**other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes**).

If a clinical study of a device product includes sites both within the United States (including any U.S. territory) and outside of the United States, and if any of those sites is using (for the purposes of the clinical study) a device product that is subject to section 510(k), 515, or 520(m) of the FD&C Act, we would consider the entire clinical study to be an applicable device clinical trial, provided that it meets all of the other criteria of the definition under this part.

However, a clinical study of a device product that is being conducted entirely outside of the United States (i.e., does not have any sites in the United States or in any U.S. territory) and is not conducted under an IDE may not be a clinical study of a device product subject to section 510(k), 515, or 520(m) of the FD&C Act and, therefore, is not an applicable device clinical trial, depending on where the device product being used in the clinical study is manufactured. **If the device product is manufactured in the United States** or any U.S. territory, and is exported for study in another country (whether it is exported under section 801(e) or section 802 of the FD&C Act), the device product is considered to be subject to section 510(k), 515, or 520(m) of the FD&C Act. If the device product is manufactured outside of the United States or its territories, and the clinical study sites are all outside of the United States and/or its territories, the device product would not be considered to be subject to section 510(k), 515, or 520(m) of the FD&C Act. A device product that is packaged and/or labeled in the United States would be considered “manufactured” in the United States subject to section 510(k), 515, or 520(m) of the FD&C Act.

Parties involved

World Health Organization

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World Health Organization

International Clinical Trials Registry Platform (ICTRP)

http://www.who.int/ictrp/network/primary/en/

Primary Registries in the WHO Registry Network

Primary Registries in the WHO Registry Network meet specific criteria for content, quality and validity, accessibility, unique identification, technical capacity and administration. Primary Registries meet the requirements of the ICMJE.

The registries that currently meet these criteria are:

Australian New Zealand Clinical Trials Registry (ANZCTR)
Brazilian Clinical Trials Registry (ReBec)
Chinese Clinical Trial Registry (ChiCTR)
Clinical Research Information Service (CRiS), Republic of Korea
Clinical Trials Registry - India (CTRI)
Cuban Public Registry of Clinical Trials(RPCEC)
EU Clinical Trials Register (EU-CTR)
German Clinical Trials Register (DRKS)
Iranian Registry of Clinical Trials (IRCT)
ISRCTN.org
Japan Primary Registries Network (JPRN) (in Japanese)
Network members: UMIN CTR Website, JapicCTI Website, JMACCT CTR Website
Thai Clinical Trials Registry (TCTR)
The Netherlands National Trial Register (NTR)
Pan African Clinical Trial Registry (PACTR)
Sri Lanka Clinical Trials Registry (SLCTR)

World Health Organization

http://www.who.int/ictrp/network/primary/en/

International Clinical Trials Registry Platform (ICTRP)

1. EU Clinical Trials Register
   https://www.clinicaltrialsregister.eu/

2. ClinicalTrials.gov

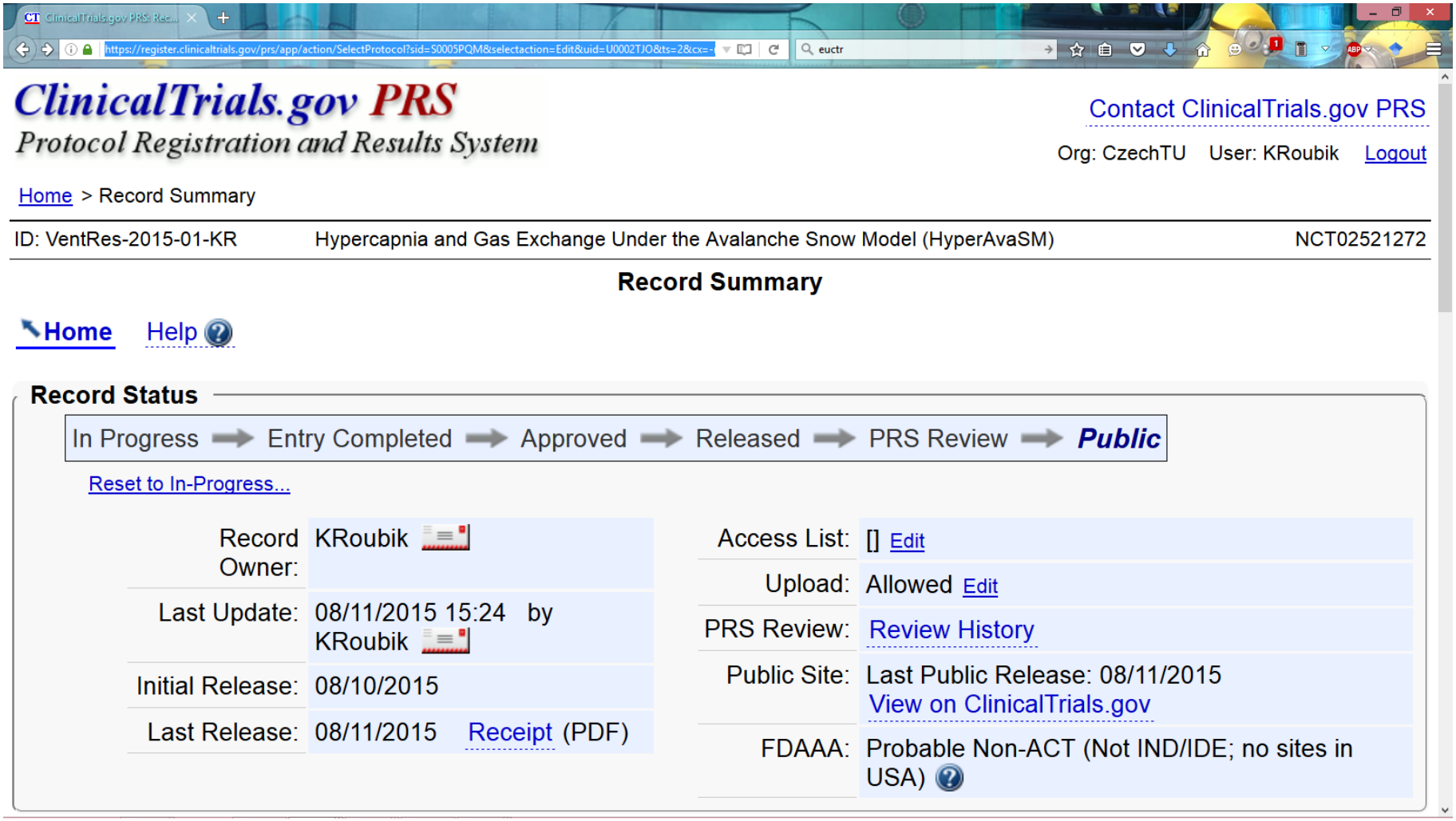
   https://clinicaltrials.gov/

Roles in the register:

- (Principal) investigator or sponsor
  (must be approved by an administrator)

- administrator (within an organization/institute)

https://www.nih.gov/news-events/news-releases/hhs-take-steps-provide-more-information-about-clinical-trials-public



ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS

Org: CzechTU User: KRoubik Logout

Home > Record Summary

ID: VentRes-2015-01-KR Hypercapnia and Gas Exchange Under the Avalanche Snow Model (HyperAvaSM) NCT02521272

Record Summary

Home Help

Record Status

In Progress → Entry Completed → Approved → Released → PRS Review → **Public**

Reset to In-Progress...

Record Owner:	KRoubik
Last Update:	08/11/2015 15:24 by KRoubik
Initial Release:	08/10/2015
Last Release:	08/11/2015 Receipt (PDF)

Access List:	[] Edit
Upload:	Allowed Edit
PRS Review:	Review History
Public Site:	Last Public Release: 08/11/2015 View on ClinicalTrials.gov
FDAAA:	Probable Non-ACT (Not IND/IDE; no sites in USA)

ID: VentRes-2015-01-KR Hypercapnia and Gas Exchange Under the Avalanche Snow Model (HyperAvaSM) NCT02521272

Edit

Study Identification

Unique Protocol ID: VentRes-2015-01-KR

Brief Title: Hypercapnia and Gas Exchange Under the Avalanche Snow Model (HyperAvaSM)

Official Title: Hypercapnia and Gas Exchange Under the Simulated Avalanche Snow

Secondary IDs:

Edit

Study Status

Record Verification: August 2015

Overall Status: Completed

Study Start: March 2012

Primary Completion: March 2012 [Actual]

Study Completion: March 2012 [Actual]

Edit

Sponsor/Collaborators

Sponsor: Czech Technical University in Prague

Responsible Party: Sponsor

Collaborators: Charles University, Czech Republic

Edit

Oversight

FDA Regulated?: No

IND/IDE Protocol?: No

Review Board: Approval Status: Approved Approval Number: UK FTVS 077/2012
Board Name: Institutional Review Board of UK FTVS (Etická komise UK FTVS)
Board Affiliation: Institutional Review Board of UK FTVS (Etická komise UK FTVS)
Phone: +420 22017 Email: bunc@ftvs.cuni.cz

Data Monitoring?: No

Plan to Share Data?:

NOTE: Plan to Share Data?: data not entered.

Oversight Authorities: Czech Republic: State Institute for Drug Control

Edit

Study Description

Brief Summary: The aim of the study is to investigate respiratory parameters of a person in the simulated avalanche snow and consequent use of the measured data for development of a mathematical-physical model of breathing during increasing hypercapnia in the avalanche.

Detailed Description: The study is a part of a university research project aimed at studying physiological conditions and development of breathing parameters of a person breathing in the

ID: VentRes-2015-01-KR Hypercapnia and Gas Exchange Under the Avalanche Snow Model (HyperAvaSM) NCT02521272

Edit

Study Description

Brief Summary: The aim of the study is to investigate respiratory parameters of a person in the simulated avalanche snow and consequent use of the measured data for development of a mathematical-physical model of breathing during increasing hypercapnia in the avalanche.

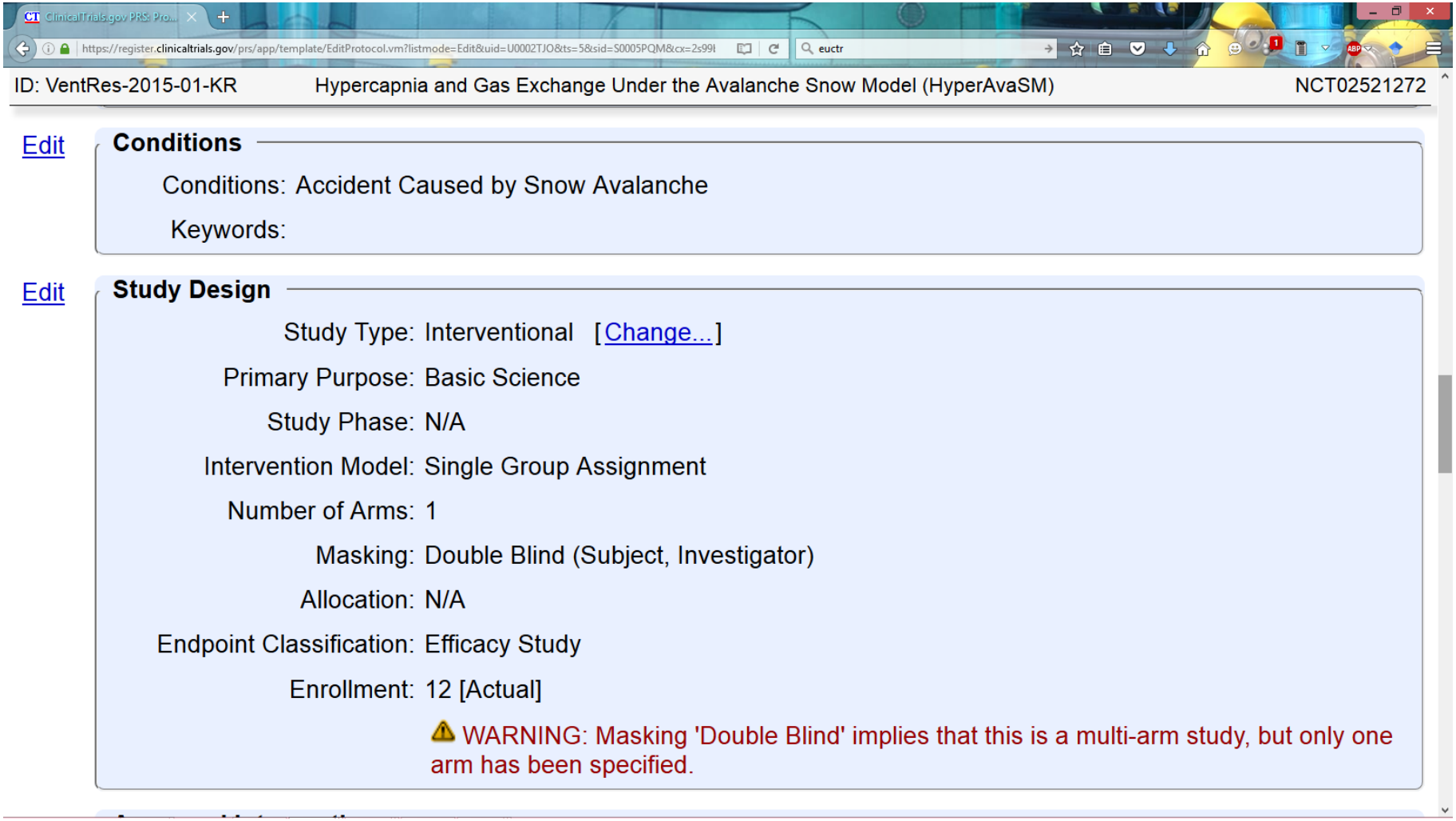
Detailed Description: The study is a part of a university research project aimed at studying physiological conditions and development of breathing parameters of a person breathing in the simulated avalanche snow. Presence of an air pocket and its size play an important role in survival of victims buried in the avalanche snow. Even small air pockets facilitate breathing, yet they do not provide a significant amount of fresh air for breathing. The investigators hypothesize that the size of the air pocket significantly affects the airflow resistance and work of breathing. The aim of the study is to investigate the effect of the air pocket volume on gas exchange and work of breathing in subjects breathing into the simulated avalanche snow and to test, whether it is possible to breathe with zero air pocket.

Edit

Conditions

Conditions: Accident Caused by Snow Avalanche

Keywords:


ClinicalTrials.gov PRS: Pro...
https://register.clinicaltrials.gov/prs/app/template/EditProtocol.vm?listmode=Edit&uid=U0002TJO&ts=5&sid=S0005PQM&cx=2s99l
euctr
ID: VentRes-2015-01-KR
Hypercapnia and Gas Exchange Under the Avalanche Snow Model (HyperAvaSM)
NCT02521272
Edit
Conditions
Conditions: Accident Caused by Snow Avalanche
Keywords:
Edit
Study Design
Study Type: Interventional [Change...]
Primary Purpose: Basic Science
Study Phase: N/A
Intervention Model: Single Group Assignment
Number of Arms: 1
Masking: Double Blind (Subject, Investigator)
Allocation: N/A
Endpoint Classification: Efficacy Study
Enrollment: 12 [Actual]
WARNING: Masking 'Double Blind' implies that this is a multi-arm study, but only one arm has been specified.

Open

Arms and Interventions

Arms	Assigned Interventions
Experimental: air pocket Breathing in the simulated avalanche snow.	Breathing in the simulated avalanche snow. Breathing in the simulated avalanche snow with zero air pocket and one-liter air pocket. Device: air pocket Zero air pocket or one-liter air pocket in the snow.

Edit

Outcome Measures

Primary Outcome Measure:

1. The length of breathing
   [Time Frame: Continuously within 30 minute interval from the beginning of the breathing experiment]
   [Safety Issue: No]
   Time to termination of the breathing experiment due to the decision of the subject, or determined by high End-Tidal CO2 value or by the order by the clinician assessing the health status of the subjects.

Edit

Eligibility

Minimum Age: 20 Years

Maximum Age: 30 Years

Edit

Eligibility

Minimum Age: 20 Years

Maximum Age: 30 Years

Gender: Male

Accepts Healthy Volunteers?: Yes

Criteria: Inclusion Criteria:

- Participants were volunteers from the Czech Army forces, studying at the Military Department of the Faculty of Physical Education and Sport, Charles University in Prague. All subjects were healthy and fit, classified as ASA I, all without a smoking history. The volunteers were highly motivated to participate in the experiment. The entrance examination, completed before the start of the study, included these tests: electrocardiography, blood pressure, spirometry, and assessment of the health conditions and family anamnesis by a physician with a specialty in anesthesia and critical care.

Exclusion Criteria:

- The exclusion criteria were Tiffeneau Index less than 0.70 and any cardiovascular or respiratory condition.

Open

Contacts/Locations

Open

Contacts/Locations

Study Officials: Karel Roubik, prof., Ph.D.
Study Director
Czech Technical University in Prague

▼Locations: **Czech Republic**

Charles University, Czech Republic
Prague, Czech Republic, 162 00

Edit

References

Citations: Brugger H, Sumann G, Meister R, Adler-Kastner L, Mair P, Gunga HC, Schobersberger W, Falk M. Hypoxia and hypercapnia during respiration into an artificial air pocket in snow: implications for avalanche survival. Resuscitation. 2003 Jul;58(1):81-8. PubMed ID: 12867313

Bellani G, Patroniti N, Weismann D, Galbiati L, Curto F, Foti G, Pesenti A. Measurement of pressure-time product during spontaneous assisted breathing by rapid interrupter technique. Anesthesiology. 2007 Mar;106(3):484-90. PubMed ID: 17325506

Grissom CK, Radwin MI, Harmston CH, Hirshberg EL, Crowley TJ. Respiration during snow burial using an artificial air pocket. JAMA. 2000 May 3;283(17):2266-71. PubMed ID: 10807386

Parties involved

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CONSORT TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomized trials

http://www.consort-statement.org/

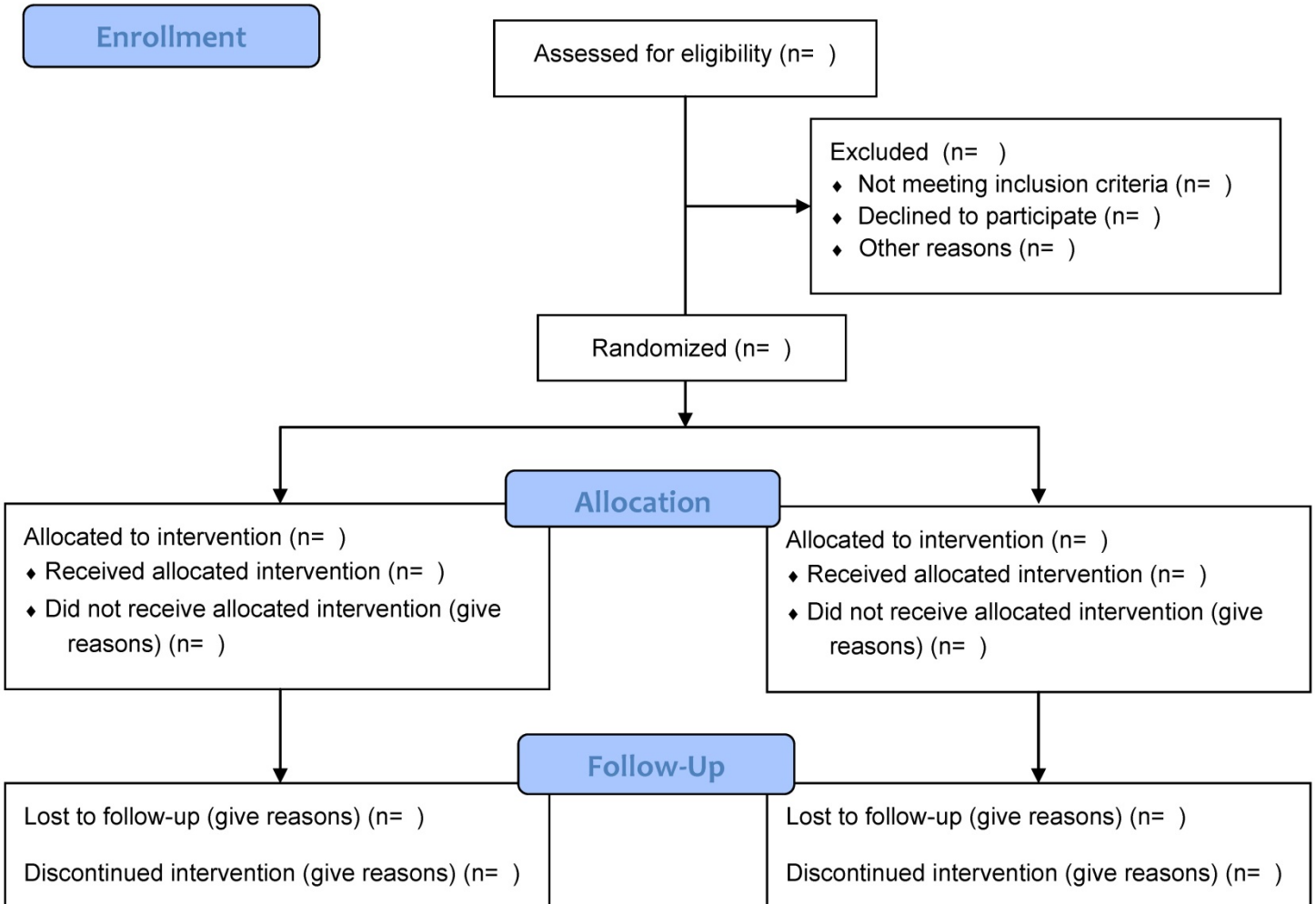
CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

CONSORT

TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram



Parties involved

World Health Organization

International Clinical Trials Registry Platform (ICTRP)

WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

ClinicalTrials.gov

EU Clinical Trials Register

...

Final Rule for FDAAA 801 and NIH Policy on Clinical Trial Reporting

CONSORT TRANSPARENT REPORTING of TRIALS

Reporting guidelines:
CONSORT
STROBE
PRISMA
STARD
EQUATOR

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals (ICMJE Recommendations)

Summary

Journals consider (almost) all studies involving human subjects as clinical trials.

According to the requirements of ICMJE and Helsinsky Declaration of WMA, the journals require that all clinical trials are registered in a ICTRP (WHO) approved database

EU Clinical Trials Register
ClinicalTrials.gov

Since January 18, 2017, the document "Clinical Trials Registration and Results Information Submission" (National Institutes of Health, Department of Health and Human Services) is effective:

If a clinical study is conducted (even partly) in the US territories OR a device under research was produces in the US, the study must be registered solely in ClinicalTrials.gov.

Journals based in the US (...) require registration in ClinicalTrials.gov; they do not accept other ICTRP (WHO) approved registers.

Summary

A study should be registered before the first subject is enrolled.

The journals require that the manuscript is prepared according to "Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals (ICMJE Recommendations)".

This document is very useful and the potential authors should know it before designing the clinical trial.

According to ICMJE Recommendations, journals require that the manuscripts are prepared (dependent on the type of the study) according to:

CONSORT for randomized trials,
STROBE for observational studies,
PRISMA for systematic reviews and meta-analyses,
STARD for studies of diagnostic accuracy.

A checklist and a flowchart is very often required during manuscript submission.

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