Informed Consent document
Case/control Group

Study name: A randomized double-blinded controlled study comparing intravenous usefulness of Acetaminophen Associated with Strong Opioids for Acute Pain in Cancer Patients.

Study sponsor/Funding source: FONIS

Qualified Investigator: Ofelia Leiva Vásquez

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AUD/Department: Internal Medicine, Pontificia Universidad Católica

The purpose of this information is to help you make a decision to participate in medical research.
Take the time you need to decide, read carefully this document and ask all the questions do you want to your doctor or another part of the study staff.

RESEARCH OBJECTIVE
You have been invited to participate in this study because you are hospitalized at our UC Christus Clinical Hospital, because you have been diagnosed with cancer and are currently with pain. The purpose of this study is to evaluate the actual benefit of intravenous Acetaminophen in the management of acute pain in cancer patients.

RESEARCH PROCEDURES

If you agree to participate in the study, the following will be done:

1. Upon admission you will be evaluated by a nurse, who will determine if you meet the criteria. If so, you will be invited to participate and you will have to sign the informed consent.
Regardless of whether you participate in the study or not, you will receive the required analgesia for their condition.

2. This study contemplates 2 groups, you will be able to be assigned to one of them completely at chance. If you are assigned to group 1, you will receive intravenous acetaminophen. If you are assigned to group 2, will receive a placebo, in this last case will receive the medicine of the same characteristics, but without the active ingredient (without acetaminophen). Neither the doctors nor the nurse Neither you nor you will know which group you were assigned to. You have a 1 in 2 chance that you will be touch the intravenous acetaminophen.

3. You will have to answer a series of surveys at the entrance of the study, at 24 and 48 hours. The Surveys are focused on evaluating pain variation, or side effects of medicines. The study will be completed within 48 hours of admission to the study.

It is important to note that standard analgesic management is indicated to all patients with pain and advanced disease, regardless of whether or not they participate in the research study.

Therefore, if required, you will be insured regardless of whether you enter the study or not.

BENEFITS

You will not directly benefit from participating in this medical research. However, the information that will be obtained will be useful to know more about the real usefulness of the acetaminophen and eventually if not useful opened scientific arguments not to indicate it.

RISKS

Your participation in this study may cause you some discomfort or uneasiness when answering the questions of the questionnaire with the topics covered in the interview.
In this case the drug studied is intravenous acetaminophen whose risks or adverse effects are very rare, as is the case of liver failure, which is dose-dependent (less than 1 person per 1000-10,000)

COST

Your participation in this study will not mean any additional costs to those already associated with the condition for which you are being treated at this center. This means that the expenses associated with your illness, diagnosis, treatment, exams, etc., are your responsibility and/or your health insurance.

DAMAGE COVERAGE

Currently your doctor prescribed acetaminophen in regular doses, with which the risk of suffering some damage is very low. In case that for reasons of the study you are assigned to follow If you receive the acetaminophen that your doctor told you about, the risk that you will be harmed is the same that it has at present. Therefore, this study does not consider giving you coverage in case present secondary damage to the acetaminophen.

There will be no compensation for complications inherent in the patient's clinical condition.

COMPENSATIONS

This study does not provide for any compensation for participation in it.

CONFIDENTIALITY OF INFORMATION

The information obtained will be kept confidential. Your name, RUN or any other identifiable information, will be coded into a database, using a computer system. This information will be stored in indefinite form under the responsibility of the Responsible Investigator Dr. Ofelia Leiva Vásquez.

It is possible that the results obtained will be presented in medical journals and conferences, however, your name will not be known.

VOLUNTARY

Your participation in this research is completely voluntary.

You have the right to refuse to participate or to withdraw your consent and withdraw from this research at any time you choose. By doing so, you do not lose any of your rights as a patient of this institution and the quality of your care will not be affected. he deserves.

If you withdraw your consent, the information obtained will not be used.

QUESTIONS

If you have questions about this medical research you can contact or call Dr. Ofelia Leiva Vásquez, responsible researcher of the study, to the email: Ofelia.leiva@gmail.com.

If you have questions about your rights -as a participant in scientific research- you can contact the president of the Scientific Ethics Committee of Health Sciences of the Pontificia Universidad Católica de Chile (CEC-Salud UC) Dr. Claudia Uribe at number +56223548173/ +56223542397 or send an email to eticadeinvestigacion@uc.cl

DECLARATION OF CONSENT

The purpose of this medical research, procedures, risks, benefits and rights have been explained to me and I may withdraw from it at any time.

I sign this document voluntarily, without being forced to do so.

I am not giving up any rights I have.

I will be informed of any new trial/study drug-related information that arises during the trial that may have direct relevance to my health condition.

I have been informed that I have the right to re-evaluate my participation in this research I will be happy to provide you with a medical opinion at any time.

I authorize the responsible researcher and his/her collaborators to access and use the data contained in my clinical file for the purposes of this medical research.

A signed copy of this document is provided to me at the time of signature.

_____	_____	_____
Name	*Signature*	*Date*
_____	_____	_____
Qualified investigator	*Signature*	*Date*
_____	_____	_____
Hospital Director (or representative)	*Signature*	*Date*