National Autonomous University of Mexico
Biomedical Research Institute

Towards the Improvement of the Treatment of Acute Relapses in Multiple Sclerosis: A Randomized Double-blind, Non-inferiority Controlled Trial Comparing Intranasal Versus Intravenous Methylprednisolone

PARTICIPANT INFORMED CONSENT FORM

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Project title: "Towards the Improvement of the Treatment of Acute Relapses in Multiple Sclerosis: A Randomized Double-blind, Non-inferiority Controlled Trial Comparing Intranasal Versus Intravenous Methylprednisolone"

Setting of the study: National Institute of Neurology and Neurosurgery (INNN), Mexico; Biomedical Research Institute (IIB), National Autonomous University of Mexico (UNAM), Mexico.

Name of the participant:

PURPOSE OF THE PARTICIPANT INFORMED CONSENT FORM

This form may include words you may not understand completely. The physician participating in the research study will describe the study to you and answer any questions you may have. Please ask the physician any question regarding words or pieces of information you don't comprehend completely.

The purpose of this form is to inform you of the details of the present research study. This form includes the purpose, procedures, benefits, risks, and warnings of the research study. Your participation in the study is voluntary. You may refuse to participate or withdraw from the study at any given time without penalty or loss of benefits regarding your medical care. Please read this informed consent form in its entirety and ask all the questions you consider necessary. In case you decide to participate in the study after reading this form, you must indicate it on the last page of this form. Do no sign this form if you have any question that has not been answered adequately.

PURPOSE OF THE STUDY

We are asking you to participate in a research study to determine whether intranasally administered methylprednisolone, the most used drug to treat active multiple sclerosis relapses, is as effective as intravenously administered methylprednisolone in symptom control and inflammation. We expect the intranasal route of administration to be more pleasant for the patient and to evoke less side effects than the intravenous administration.

Participants of the study will be randomly assigned to one of two groups, in which they will receive either intranasal or intravenous treatment. Blood samples will be drawn at three separate times in the duration of the study, as well as fecal samples. Analysis of the blood and fecal samples will provide us with information regarding inflammation levels and possible side effects. Participants will be assessed by a physician every appointment; results of the assessment will be included in their medical record.

DURATION OF THE STUDY

The study will last approximately 4 weeks. If you choose to participate, we will ask you to attend two follow-up appointments: at the end of treatment and the other one month after the beginning of treatment. The blood and fecal samples will be collected in both follow-up appointments and at the beginning of treatment. We will also require you to answer a follow-up questionnaire.

SAFETY MEASURES

To ensure your safety, you must inform the physician of every symptom of the relapse, as well as other diseases (e.g., diarrhea) you have in the duration of the study. You must specify every medical drug you take, as well as other alternative medicine practices (e.g., acupuncture).

PROCEDURE OF THE STUDY

Before receiving treatment, the physician will assess you, emphasizing on a nose inspection and the severity of multiple sclerosis relapse symptoms according to the Expanded Disability Status Scale. After the assessment, we will draw the first blood sample and provide material and instructions for you to get the first fecal sample. Subsequently, you will be assigned randomly to a treatment group: Intravenous MP or Intranasal MP, which will determine if you are receiving methylprednisolone intravenously of intranasally, respectively. The treatment will be administered for 3 to 5 days, depending on the physician assessments. At the end of treatment, we will draw the second blood sample. You will be required to answer a questionnaire regarding secondary effects, this questionnaire will be checked briefly by a physician. We will ask you to return approximately 25 days after the treatment finishes to take the third blood sample and the second fecal sample. In the last appointment a physician will assess your mobility and general clinical status, including a nose examination.

All procedures will be performed by authorized medical staff working in the National Institute of Neurology and Neurosurgery who are also participating in the study.

RISKS AND WARNINGS

Receiving the treatment intravenously may cause:

- Heart palpitations
- Swelling
- Taste distortion, especially metallic taste
- Hot flash
- Face redness
- Stomach acidity
- Insomnia

Receiving the treatment intranasally may cause:

- Irritation on the nasal cavity
- Dry nasal cavity
- Watery eyes
- Discomfort

If you experiment any of these symptoms, you must notify the physician as soon as you can.

BENFITS OF THE STUDY

Your participation in this study will help to determine whether the intranasal route of treatment is an efficient and less invasive way to control the symptoms associated to multiple sclerosis relapses. The intranasal route has a direct connection to the central nervous system, which confers it with the potential to control the inflammation effectively with a smaller dose, reducing adverse effects.

CONFIDENTIALITY AGREEMENT

The personal information used for this study, including your identity, is confidential. If you sign this informed consent form, you allow us to share the information obtained from the samples and assessments with researchers participating in the study. If the results of this study are published in an article, your identity will not be revealed.

LEGAL RIGHTS

You are not renouncing any legal right by signing this informed consent form.

VOLUNTARY PARTICIPATION

Your decision to participate in this research study is completely voluntary. You will not receive any form of penalty or loss of benefits regarding your medical care if you choose not to participate.

You may withdraw from the study at any given time. There will be no sanction of any form if you decide to leave the study.

PARTICIPANT INFORMED CONSENT STATEMENT

I have been informed that my participation in this study is voluntary and that should I decide to not participate in the study or withdraw form it, I will not receive any kind of punishment or loss of benefits.

I have read this informed consent form and all my questions have been answered adequately. I agree to participate in this study after understanding the benefits and risks. I have been informed that researchers participating in this study will have access to my

medical record. I give permission to publish the information obtained from my blood and fecal samples in this study.

SIGNATURES

Name of the participant	Date	Signature or fingerprint
Address of the participant	Participant phone number	

Name of witness no. 1	Date	Signature or fingerprint
Address of witness no. 1	Relationship to the participant	

Name of witness no. 2	Date	Signature or fingerprint
Address of witness no. 2	Participant phone number	

Name of the authorized medical staff	Date	Signature