



# Autonomous University of the State of Mexico

Faculty of Medicine

Clinical protocol:

**“Effect of vitamin C, vitamin D and Zinc supplementation on the immune and inflammatory process in type 2 diabetic subjects in Mexico”.**

## INFORMED CONSENT

Researchers:

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Toluca, State of Mexico, November 5, 2018

## INFORMED CONSENT

Title of project:

**Effect of vitamin C, vitamin D and Zinc supplementation on the immune and inflammatory process in type 2 diabetic subjects in Mexico.**

We invite you to participate in this study. If you decide to participate in this study, it is necessary to carefully read the following informed consent and ask the researchers if you have any questions.

**-What is the objective of project?**

To evaluate the effect of vitamin C, vitamin D and Zinc in patients with type 2 diabetes mellitus.

**-What is the project about?**

This study is about supplementation with vitamin C, vitamin D and zinc for 6 months, in patients with type 2 diabetes mellitus. If you decide to participate, you will have to give a faecal sample, information on food habits and clinical data. Additionally, we will measure your weight, height, waist and hip circumferences. Also, we will take blood sample from your arm.

We will be taking three measurements: at baseline (before supplementation), at 12 and 24 weeks after supplementation at the outpatient preventive medicine offices of Medical Center "Adolfo Lopez Mateos" in Toluca, State of Mexico.

**-How will you be receiving supplementation of vitamin C, vitamin D and zinc?**

There are two groups: A first group receiving daily effervescent tablets containing vitamin C, vitamin D and Zinc; another group will receive similar effervescent tablets without vitamin C, vitamin D and zinc. Subjects will be randomly assigned to each group.

**-Who can participate in this study?**

Subjects from both genders (woman or men) with type 2 diabetes mellitus, aged between 25 to 55 years, and body mass index  $\geq 25$ . Without other chronic diseases.

**-Who is paying for the study?**

The Autonomous University of the State of Mexico will pay for everything related to the project. All measurements will be free for you.

**-What is the risk, if you decide to participate in the project?**

The supplementations with vitamin C, vitamin D and zinc will be given a low doses, however, there is a probability that you may present adverse effects such as: nausea, vomit, diarrhea, metallic flavor, and stomach pain or energy loss. Adverse effects will also be registered during the monthly follow-up visits. If an adverse effect that puts you at risk is identified, such as an allergy, the supplementation will be suspended and reported to the authorities

**-What can I do, if I present any adverse effect?**

Call Dr. Roxana Valdes Ramos.

Phone number: 2175152 ext. 232

**-What benefits can I expect?**

According to several reports Vitamin C, vitamin D and zinc supplementation may improve glucose and insulin levels and could prevent complication from diabetes mellitus. Additionally, the studies reported that these supplements decrease glycated hemoglobin and could improve the quality of life of those patients consuming them.

After each measure we will deliver you the results on: glucose, insulin, glycated hemoglobin, weight, height, waist and hip circumference.

**-Who can I call, if I have any questions?**

A Dr. Roxana Valdes Ramos

Phone number: 2175152 ext. 232

**-Can I refuse to participate in this study?**

Yes, you can. The participation is voluntary and if you do not want to participate in this project you can do it and there will be no problem.

**-Who can see my information?**

Individual results will not be shared with anyone at any time. The information will be used for research and general reporting

**-What are your doing with the blood and fecal samples?**

The samples will be stored frozen in the Nutrition Research Laboratory of the Faculty of Medicine of the Autonomous University of the State of Mexico until all measurements are completed

**-May I know my results when the ending project?**

Yes, when the project is ended, you may know the results about the blood and fecael samples if you want.

**If I sign the follow informed consent, I accept that:**

- I have read this informed consent
- I have had the opportunity to ask questions and have received adequate and sufficient answers
- My participation in this study is voluntary
- I accept to participate in the study
- I can choose accept or not accept to participate in the study and I can leave when I want.

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Participant signature

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Date

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Dr. Roxana Valdés Ramos (Responsible of project)

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Witness name and signature

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Date

Address

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Relationship with the volunteer

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Witness name and signature

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Date

Address

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Relationship with the volunteer

Received copy this document

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Name and signature

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Date