Official title: Adherence to Guidelines Vaccination in Type 1 Diabetes Mellitus Patients (AVADI).

NCT number: NCT03478254

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Informed Consent form for men and women who attend Diabetes consult at the Ciudad Real General University Hospital, and who we are inviting to participate in research on aadherence to guidelines vaccination. The title of our research project is "Adherence to Guidelines Vaccination in Type 1 Diabetes Mellitus Patients"**.**

Name of Principal Investigator: Dr. Jesus Moreno Fernandez.
Name of Organization: Castilla-La Mancha Public Health Service.
Name of Sponsor: Ciudad Real General University Hospital.
Unique protocol identification: C-127

You will be given a copy of the full Informed Consent Form

Information Sheet

Introduction

I am Dr. Jesús Moreno Fernandez, working for the Ciudad Real General University Hospital. We are doing research on type 1 diabetes. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or the staff.

Purpose of the research

Type 1 diabetes patients have an increased risk for certain types of infections, including flue, pneumonia and hepatitis. Because of that, type 1 diabetes persons are recommended for vaccination against these diseases. The adherence to vaccination recommendations remains unknow. Therefore, we are conducting this study.

Type of Research Intervention

This research will involve a that your clinical data will be collected in order to analyse if you are or not vaccinated against these diseases.

Participant selection

We are inviting all adults type 1 diabetes persons attended in our Hospital.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will offered the same assistance that is routinely offered in this clinic/hospital for type 1 diabetes, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

Procedures and Protocol
No medication or extra medical assistance will be necessary if you want to participate in this study. We will only collect and analyze your medical data regarding your vaccination state.

Duration
The research takes place over one year in total. During that time, it won´t be necessary for you to come additional days to the hospital

Side Effects
No side effects are expected.

Risks
By participating in this research, it is not possible that you will be at greater risk than you would otherwise be.

Benefits
There may not be any benefit for you, but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

Reimbursements
We will not give you any reimbursements for participate in the research.

Confidentiality
With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one, but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is, and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].)

Sharing the Results
The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be

shared. There will be small meetings in the community, and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.)

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.

Alternatives to Participating

If you do not wish to take part in the research, you will be provided with the established standard assistance available at the hospital.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: Angela Mª Seco Segura, Diabetes Consultant, Ciudad Real General University Hospital, 13005, Ciudad Real, Spain, number: 0034-926278000.

This proposal has been reviewed and approved by Ciudad Real General Hospital Ethic Board Committee, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the Ethic Board Committee, contact Cristobal Martinez, Ciudad Real General University Hospital, 0034-926278000.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

Certificate of Consent to Participate in the study "Adherence to Guidelines Vaccination in Type 1 Diabetes Mellitus Patients"

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

If illiterate
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumbprint as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent
I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:
1. Participate in the study.
2. Only clinical data will be gathered.
3. Extra risks do not exist.
I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year