This Informed Consent Form is for parents of children who are less than 14 years old diagnosed with T1DM and who attend endocrinology outpatients' clinic at Al-Rantisi Pediatric Hospital in the Gaza Strip.

RESEARCH INFORMATION

Research Title:

The Effects of Vitamin D Supplementation on Glycemic Control in Children with Type 1 Diabetes Mellitus in Gaza Strip, A Randomized Controlled Trial.

Authors:

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Running title:

Vitamin D Supplementation and Glycemic Control Improvement among Type 1 Diabetic Children.

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PART I: INFORMATION SHEET

INTRODUCTION

I am **Heba AbdAllah Al Sarraj**, working for the Department of Laboratory Medicine, Al Azhar University-Gaza, Gaza Strip, Palestine. We are researching Type 1 Diabetes Mellitus, which is very common in our country. According to World Diabetes Foundation, in Palestine, 4.4% of diabetic patients are diagnosed with T1DM. I am going to give you information and invite your child to be a part of this research. You do not have to decide today whether or not your child 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 about me, the study doctor or the staff.

PURPOSE OF THE STUDY

The purpose of this study is to screen for vitamin D deficiency and to examine the effects of vitamin D supplementation on glycemic control among children with T1DM in the Gaza Strip.

TYPE OF RESEARCH INTERVENTION

This research will involve a blood draw from your child's arm as well as follow-up visits to the clinic. In addition, the interventional group will be supplemented with vitamin D tablets containing 2000 IU once time daily with a meal, for 3 months of intervention.

PARTICIPANT SELECTION

A stratified random sampling technique will be applied to assign children who are less than 14 years old, diagnosed with T1DM which are indicated through fasting blood glucose levels greater than 126 mg/dl or HbA1c cut point of ≥6.5% (American Diabetes Association, 2010), and had vitamin D deficiency which indicated by its levels of less than 12 ng/ml (Sullivan, 2019), are recruited from endocrinology outpatients' clinic at Al-Rantisi Pediatric Hospital in the Gaza Strip.

VOLUNTARY PARTICIPATION

Your child's participation in this research is entirely voluntary. It is your choice whether your child to participate or not. Whether you choose your child to participate or not, all the services he or she receives at this clinic will continue and nothing will change. If you choose your child not to participate in this research project, you will be offered the treatment that is routinely offered in this clinic/hospital for T1DM. You may change your mind later and stop participating even if you agreed earlier.

PARTICIPANTS CRITERIA

The researcher in charge of this study or a member of the study staff will be discussed with you the requirements for your child to participate in this study. You must be completely truthful with the researcher and staff about your child's health history. Your child shouldn't participate in this study if he or she did not meet all eligibility criteria.

The eligibility criteria are:

Criteria for children with T1DM:

Inclusion criteria for children with T1DM:

1- Children (4-14 years of age) of both gender, with a T1DM.
2- Not on vitamin D supplementaition.

Exclusion criteria for children with T1DM

1. Age ≤ 4 or more than14 years old
2. Patients with T2DM
3. Children had received vitamin D supplements

STUDY PROCEDURES

Participants' parents will provide with a research information sheet, questionnaires, and acceptance form. You are required to answer all the questions truthfully and sign the acceptance form if you voluntarily decide your child to participate in this study, then the questionnaire will be filled, anthropometric measurements and a blood sample will be taken, this process will take nearly half an hour for each participant.

The blood sample collection process began with blood collection at the endocrinology outpatients' clinic at Al-Rantisi Pediatric Hospital in the Gaza Strip, then the samples will be transferred under suitable conditions to avoid high or low-temperature exposure, to the Palestinian Medical Relief Society (PMRS) laboratory, where blood tests will performed.

About 80 children diagnosed with T1DM will be chosen to participate in this study. If you agree to take part in this study, Five-ml of venous blood samples will be obtained from each child by venipuncture under quality control and safety procedures by a qualified nurse and divided into two tubes. About one ml was placed into an Ethylene diamine tetraacetic acid (EDTA) vacutainer tube to perform the HA1c test. Three milliliters will be placed in plain red top tubes and centrifuged at 3000 rpm for 10 min as soon as they had been collected. The serum will be separated and analyzed immediately. Vitamin D level will be performed on the Fully-auto chemiluminescence immunoassay (CLIA) analyzer MAGLUMI. The blood taking will be done twice at the first visit and after 3 months and the samples will be destroyed at the end of the study. The duration of participation in the study will be from the moment they participate in the study until they are given the results.

DESCRIPTION OF THE PROCESS

During the research, you make two visits to the clinic.

- In the first visit, a small amount of blood will be taken from your child's arm with a syringe. This blood will be tested for HbA1c and vitamin D. We will also ask you a few questions about your child general health and measure how tall your child is and how much your child weighs then your child will be

categorized into two groups; Group A: is the interventional group that will be supplemented with vitamin D tablets contain 2000 IU once time daily with a meal, for 3 months of intervention, and Group B: is the control group, that will not receive any type of supplements during the intervention period.

- At the next visit, which will be three months later, your child will come back to the clinic for a blood test. This will involve HbA1c and vitamin D for follow-up.

DURATION

The research takes place over three months in total. during that time, it will be necessary for your child to come to the clinic two days for one hour each day. We would like to meet you three months after your last clinic visit for a final check-up.

In total, you will be asked to come 2 times to the clinic in 3 months. at the end of three months, the research will be finished.

RISKS

The risk of this study is minimum. For most people, a needle puncture for blood taking usually doesn't cause any serious problems. However, they may cause redness, bruising, discomfort or itchiness, pain at the needle site, or dizziness which may disappear within several hours or days.

REPORTING HEALTH EXPERIENCES

If your child has any bad effects, or any other unusual health experience during this study, make sure that you immediately tell the nurse or researcher Heba Mohammed Jawad Arafat, at 00972 599575745. You can call at any time, day or night, to report such health experiences.

PARTICIPATION IN THE STUDY

Your child taking part in this study is entirely voluntary. You may refuse your child to take part in the study or you may stop your child participate in the study at any time, without any penalty or loss of benefits to which your child is otherwise entitled.

Your child participation also may be stopped by the researcher without your consent if in any form you have violated the study eligibility criteria.

POSSIBLE BENEFITS

If your child participates in this research, your child will have the following benefits: your child's T1DM follow-up during the study period will be free of charge. Sample drew and study procedures will be provided at no cost to your child. There may not be any benefit for you but your child participation is likely to help us find the answer to the research question. There may not be any benefit to society at this stage of the research, but future generations are likely to benefit.

QUESTIONS

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:

Miss. Heba Mohammed Arafat
Department of Laboratory Medicine
Faculty of Applied Medical Sciences
Al- Azhar University- Gaza
Mobile NO.: 00972599575745
Email: hebaarafat4@hotmail.com

If you have any questions regarding the Ethical Approval or any issue/problem related to this study, please contact;

Dr. Nasser Abu Shaaban
Chairman of Palestinian of Ethical Committee
(Helsinki Ethics Committee)
Gaza/Palestine
Email: pal.phrc@gmail.com

OR

Prof. Nahed Al Laham
Member of Palestinian of Ethical Committee

(Helsinki Ethics Committee)
Gaza/Palestine
Mobile NO.: 00970599560533
Email: n.lahamm@alazhar.edu.ps

CONFIDENTIALITY

Your child's medical information will be kept confidential by the study researcher and will not be made publicly available unless disclosure is required by law. Data obtained from this study that does not identify your child individually will be published for knowledge purposes. Your child's original medical records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities to verify the study procedures and/or data. Your child's information may be held and processed on a computer.

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 so that other interested people may learn from our research.

RIGHT TO REFUSE OR WITHDRAW

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

By signing this consent form, you authorize the record review, information storage, and data process described above.

Thank You

Signature of participant

Date:

PART II: Certificate of Consent

To be entered into the study, you or a legal representative must sign on the signature page.

Subject Information and Consent Form

(Signature Page)

Research Title: **The Effects of Vitamin D Supplementation on Glycemic Control in Children with Type 1 Diabetes Mellitus in Gaza Strip, A Randomized Controlled Trial.**

Main Researcher : **Heba AbdAllah Al Sarraj**

Co Researchers: **Ashraf Jaber Shaqaliah,**
Heba Mohammed Arafat,
Ohood Mohammed Shamallakh, and
Kholoud Mohammed Shamallakh.

To become a part of this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form including any information regarding the risk in this study and I have had time to think about it. All of my questions have been answered to my satisfaction.
- I voluntarily agree to be a part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at any time.
- I have received a copy of this Participant Information and Consent Form to keep for myself.

_____

Participant Name

_____

Participant I.C No.

_____ _____

Signature of Participant or Legal Representative **Date (DD/MM/YY)**

_____

Name of Individual conducting Consent Discussion

_____ _____

Signature of Individual Conducting Consent Discussion **Date (DD/MM/YY)**

_____ _____

Name & Signature of Witness **Date (DD/MM/YY)**

Note: i) All participants who are involved in this study will not be covered by insurance.

Subject Information and Consent Form

(Signature Page – Blood Sample)

Research Title: **The Effects of Vitamin D Supplementation on Glycemic Control in Children with Type 1 Diabetes Mellitus in Gaza Strip, A Randomized Controlled Trial.**

Main Researcher : **Heba AbdAllah Al Sarraj**

Co Researchers: **Ashraf Jaber Shaqaliah,**
Heba Mohammed Arafat,
Ohood Mohammed Shamallakh, and
Kholoud Mohammed Shamallakh.

To become a part of this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form including any information regarding the risk in this study and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at any time.
- I have received a copy of this Participant Information and Consent Form to keep for myself.

_____

Participant Name

_____ _____

Participant I.C No.

_____ _____

Signature of Participant or Legal Representative **Date (DD/MM/YY)**

_____

Name of Individual conducting Consent Discussion

_____ _____

Signature of Individual Conducting Consent Discussion **Date (DD/MM/YY)**

_____ _____

Name & Signature of Witness **Date (DD/MM/YY)**

Note: i) All participants who are involved in this study will not be covered by insurance.

ii) Excess samples from this research will not be used for other reasons and will be destroyed with consent from the Human Research Ethics Committee, USM.

Participant's Material Publication Consent Form

Signature Page

Research Title: **The Effects of Vitamin D Supplementation on Glycemic Control in Children with Type 1 Diabetes Mellitus in Gaza Strip, A Randomized Controlled Trial.**

Main Researcher : **Heba AbdAllah Al Sarraj**

Co Researchers: **Ashraf Jaber Shaqaliah,**
Heba Mohammed Arafat,
Ohood Mohammed Shamallakh, and
Kholoud Mohammed Shamallakh.

To become a part of this study, you or your legal representative must sign this page.

By signing this page, I am confirming the following:

- I understood that my name will not appear on the materials published and there have been efforts to make sure that the privacy of my name is kept confidential although the confidentiality is not completely guaranteed due to unexpected circumstances.
- I have read the materials or general description of what the material contains and reviewed all photographs and figures in which I am included that could be published.
- I have been offered the opportunity to read the manuscript and to see all materials in which I am included but have waived my right to do so.

- All the published materials will be shared among medical practitioners, scientists, and journalists worldwide.

- The materials will also be used in local publications, book publications and accessed by many local and international doctors worldwide.
- I hereby agree and allow the materials to be used in other publications required by other publishers with these conditions:

- The materials will not be used for advertising purposes nor as packaging materials.

- The materials will not be used out of context – i.e.: Sample pictures will not be used in an article that is unrelated subject to the picture.

_____

Participant Name

_____ _____

Participant I.C No.

_____ _____

Signature of Participant or Legal Representative **Date (DD/MM/YY)**

_____

Name of Individual conducting Consent Discussion

_____ _____

Signature of Individual Conducting Consent Discussion **Date (DD/MM/YY)**

_____ _____

Name & Signature of Witness **Date (DD/MM/YY)**

Note: i) All participants who are involved in this study will not be covered by insurance.