INFORMED CONSENT FORM

Intralesional Therapies for Cutaneous Viral Warts: A Comparative Analysis of Vitamin D_3 and Acyclovir

Official Title: Intralesional Therapies for Cutaneous Viral Warts: A Comparative Analysis of Vitamin D_3 and Acyclovir

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Multicenter Randomized Controlled Trial

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Site 2: Riphah International Hospital, Sector A DHA Phase 5, Islamabad
Site Investigator / **Co-PI:** Dr. Fatima Sajid
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INFORMED CONSENT FORM

1. Introduction

You are being invited to take part in a research study. Before you decide whether to participate, it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information carefully. You may ask questions if anything is unclear or if you would like more information.

2. Purpose of the Study

The purpose of this study is to compare two treatments for skin warts: acyclovir (an antiviral medicine) and vitamin D3, both given as injections directly into the wart. The study aims to find out which treatment is more effective at clearing warts and which has fewer side effects. This study is being conducted at two hospitals: Pakistan Railway Hospital and Riphah International Hospital, Islamabad.

3. Why Have I Been Invited?

You are being invited because you have been diagnosed with skin warts (common warts, plantar warts, flat warts, or warts around the nails) and are aged 12 years or older. About 40 people across both hospitals will take part in this study.

4. Do I Have to Take Part?

No. Participation is entirely voluntary. You are free to decide whether or not to take part. If you do decide to take part, you will be asked to sign this consent form. You are free to withdraw at any time, without giving a reason and without your medical care being affected.

5. What Will Happen If I Take Part?

If you agree to take part, you will be randomly placed into one of two treatment groups:

- **Group A:** You will receive acyclovir injections into your wart(s)
- **Group B:** You will receive vitamin D3 injections into your wart(s)

You will receive an injection every 2 weeks for up to 4 sessions (8 weeks). The amount injected will depend on the size of your wart. Photographs of your warts will be taken at each visit. You will be followed up for a total of 3 months.

6. What Are the Possible Risks and Side Effects?

As with any injection, you may experience some side effects at the injection site, including:

- Pain or discomfort during or after injection
- Redness (erythema)

- Swelling
- Ulceration (rare)
- Scarring (rare)

The research team will monitor you for any side effects at each visit. If you experience any unexpected symptoms, you should contact the research team immediately.

7. What Are the Possible Benefits?

The treatment may help to clear your warts. However, there is no guarantee that you will benefit from taking part. The information gathered from this study may help improve treatment for people with warts in the future.

8. Confidentiality

All information collected about you during the study will be kept strictly confidential. Your data will be identified by a code number only. Your name will not appear in any report or publication resulting from this study. Photographs taken of your warts will be stored securely and identified by code only. Your data may be shared between the two study sites in a de-identified form for the purpose of combined analysis.

9. What Will Happen to the Results?

The results of this study may be published in a medical journal and presented at conferences. You will not be identified in any report or publication. A summary of the results can be made available to you upon request.

10. Who Has Reviewed This Study?

This study has been reviewed and approved by the Institutional Ethical Review Committee.

11. Contact Information

If you have any questions about the study, your participation, or your rights as a research participant, please contact:

Principal Investigator: Dr. Nadia Ghazanfar
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CONSENT DECLARATION

I confirm that I have read and understood the information provided above for this study. I have had the opportunity to ask questions and have had them answered satisfactorily. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care being affected. I agree to take part in this study.

_____	_____
Name of Participant	Date
_____	_____
Signature of Participant	Study Site
_____	_____
Name of Person Taking Consent	Date
_____	
Signature	

PARENTAL/GUARDIAN CONSENT AND MINOR ASSENT

For participants aged 12-17 years, the following additional consent is required:

I, the parent/legal guardian, confirm that I have read and understood the information provided for this study. I give consent for my child to participate in this study.

_____	_____
Name of Parent/Guardian	Date
_____	_____
Signature of Parent/Guardian	Study Site
_____	_____
Name of Minor Participant	Date
_____	
Signature/Assent of Minor	