

## DOUBLE BLIND PLACEBO CONTROLLED CLINICAL TRIALS OF HOMOEOPATHIC MEDICINES IN WARTS AND MOLLUSCUM CONTAGIOSUM

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### Introduction

Wart is one of the common dermatological disorders caused by DNA viruses, which grow in the epidermis. The source of infection is other infected individuals and the disease is transmitted by direct or close contact. It has very low infectivity ; a casual contact with an infected individual is unlikely to result in the disease. The virus enters into the skin through minor or microscopic injuries. Clinically the lesions are asymptomatic and manifest in different forms, have irregular verrucous surface and keep on growing slowly. The number of warts varies from single to several hundred. The individuals with depressed cell-mediated immunity due to treatment with immunosuppressive drugs, Hodgkins' disease, malignant lymphomas and lymphocytic leukaemia are more likely to have a large number of warts. The different varieties of warts include the following :

*Common Warts or Verruca Vulgaris* : These are characterised by firm, skin colour papules of various sizes with verrucous surfaces and can occur on any part of the body but are most commonly present on the dorsum of the hands and fingers.

*Plain Warts or Verruca Plana* : It presents as skin coloured, slightly raised flat-topped papules and are usually present on dorsum of hand and face.

*Filiform Warts* : These are finger like projections with irregular surface and are usually seen on the neck, face and scalp.

*Plantar Warts* : These are found on any part of the sole. The lesions are occasionally painful. The warts present as skin coloured well defined areas in the sole with irregular surface.

*Genital Warts* : These warts are usually transmitted through sexual contact. These are present as fungating masses of verrucous tissue. Tissue on glans penis, corona, mucosal surface of prepuce and occasionally on the urinary meatus in males, and the vulva and vaginal openings in the females.

*Molluscum Contagiosum* : Large virus belonging to the pox group of viruses causes it. It gets implanted on the skin by contact with an infected individual. Auto - inoculation after infection is very common which causes the spread of the disease to the different parts of the body. The disease is common in children. When it is present on the genitals of an adult male or female, transmission is usually through sexual exposure. It manifests in the form of asymptomatic, pearly white or pink papules with well-defined depressed centers known as umbilication. After trauma or spontaneously after a few months, inflammatory changes result in suppuration and crusting leading to destruction and disappearance of the lesions.

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The course of *Warts* and *Molluscum Contagiosum* is unpredictable, peculiar and inconsistent. Therefore it is often difficult to evaluate the results of any treatment. The various modalities are available for the treatment of warts in various systems of medicine which include electrocoagulation, cryosurgery<sup>1</sup>, curetage<sup>2</sup>, trichloroacetic acid, silver nitrate, podophyllin urea<sup>3</sup>, formalin soaks<sup>4</sup>, vitamin A acid application<sup>5</sup>, calcium hydroxide solution soaks<sup>3</sup>, bleomycin local injection<sup>6</sup> and hypnosis<sup>3,7</sup>. It is known that Homoeopathic drugs are very effective for the treatment of Warts/*Molluscum contagiosa*. Many cases and reports are available confirming the efficacy but no report is based on double blind study<sup>8,9,10</sup>. In a study undertaken during 1986-88, 10 revealed that some of the homoeopathic medicines were found 75-90% effective in the treatment of different types of warts. Keeping in view the possibility of spontaneous remissions in warts it is desirable that a double blind placebo controlled trial is conducted with the drugs found very useful in the treatment of warts/molluscum.

### **Aims and Objectives**

- 1) To evaluate the efficacy of selected homoeopathic drugs found useful in the treatment of warts in open clinical trials using controlled trials.
- 2) To evaluate the efficacy of *Calcarea carbonicum* in the treatment of *Molluscum contagiosum*

### **Material and Methods**

A problem oriented proforma having provision of recording all the symptoms pertaining to warts and the person as a whole was designed and used in the trials. The duration, size, number, sensations in the warts in respect of each case was recorded on this proforma. All the cases were diagnosed and assessed clinically.

### **Study Designs**

**Two types of placebo controlled double blind clinical trials were undertaken.**

- Cross over design : The subjects were given both drug and the placebo. This study was carried out during 1995-96.
- Parallel design : One group received the drug and other group received placebo. This trial was carried out during 1996-97.

Both the trials were carried out at Nehru Homoeopathic Medical College & Hospital, New Delhi

#### *Inclusion Criteria*

- Any age group
- Cases of *Verruca Vulgaris*, *Verruca Plana*, *Verruca filiformis*, *Verruca plantaris* and *Verruca genitalis*.
- Cases of *Molluscum Contagiosum*.

#### *Exclusion Criteria*

- Cases on immunosuppressive drugs
- Cases having active treatment for other diseases.

## Project Report 1

The study was started in May '95 and concluded on 30th April '96. 60 cases (35 males, 25 females) having different types of warts were registered. Results of 43 cases (25 males, 18 females) were analysed and 17 cases were dropped out.

All the cases were given pre-coded (*Thuja*, *Ruta*, *Calcarea carbonicum*, *Dulcamara*, *Nitric acid*, *Causticum*) drugs or pre-coded placebo at random for a period of 15 days. The precoded drugs of 30 potency were given in TDS dose, 200 potency was used in BD doses and 1M potency was used in OD doses.

### Prescribing indications used

*Calcarea carbonicum* was given to all the cases of Molluscum contagiosum.

*Ruta* was used for smooth warts on face and palms, and plantar warts having soreness.

*Nitric acid* was used for common warts having cauliflower like appearance, hard, large and bleeding easily.

*Dulcamara* was given for plain fleshy warts on face and hands.

Causticum was used for small as well big warts over hands and peri - ungual region.

*Thuja* was used in all other cases of warts having different types of locations, irrespective of any constitutional indications.

After decoding the experiment the details of the responses received are as under :

Results after decoding the treatment										
Cases	Total	100%	Active Drug Group	Resp. in %	Placebo Group	Resp in %	Drug-Plac. Group	Resp in %	Only Plac.	Resp in %
Verruca Vulgaris	21	18	10	55.56	8	44.44	7	38.89	1	5.56
Verruca Plana	07	04	03	75.00	1	25.00	1	25.00	0	0.00
Verruca Plantaris	05	03	02	66.67	1	33.33	0	0.00	1	33.33
Molluscum Cont.	10	08	06	75.00	2	25.00	2	25.00	0	0.00
<b>Total</b>	<b>43</b>	<b>33</b>	<b>21</b>	<b>63.64</b>	<b>12</b>	<b>36.36</b>	<b>10</b>	<b>30.30</b>	<b>2</b>	<b>6.06</b>

## Observations

- 63.6% cases improved with active drug and 36.36% cases improved with placebo in our study. The improvement indices of active drug group are far better than the placebo group which clearly indicates that the homoeopathic drugs definitely possess power to cure warts and Molluscum contagiosum.
- In this research study design, each case was initially given a drug code in 30 potency which could be either active drug or placebo. If the cases did not improve with this code, the next code of 200 potency was given which could again be either active drug or placebo. Therefore it was found after decoding, that some cases who were initially on active drug code in 30 potency received placebo in the next drug code of 200 or 1M potency or vice versa.
- Among 36.36% improved cases under the placebo group, it was found that 30.30% received an active drug in the preceding drug code and therefore this could be attributed to carry over effects of active drug. Only 6% improved cases under placebo group were found to be only on placebo throughout the trial period. This observation is very significant.

## Project Report 2

The study was started in May '96 and concluded on 30th April '97. 124 cases (81 males, 43 females) having different types of warts and Molluscum contagiosum were registered. Results of 104 cases (71 males, 33 females) were analysed and 20 cases were dropped out.

All the cases were given pre-coded drug *Thuja*, *Ruta*, *Calcarea carbonicum* and *Causticum* following double blind placebo controlled study, parallel design for a period of 15 days. The pre-coded drugs in 30 potency were given in TDS doses, 200 potency was used in BD doses and 1M potency was used in OD doses.

This study had much larger size than the previous one and care was taken to avoid carry over effects of homoeopathic medicines adopting different research design.

The data pertaining to reporting cases is as follows :

Drugwise Response after Decoding									
Drug	Total	Res ponse	%	Drug	Res ponse	%	Placebo	Res ponse	%
Thuja	42	24	57	27	22	81	15	05	33
Caust.	29	17	58	19	13	68	10	04	40
Ruta	13	09	69	10	07	70	03	02	66
Cal.carb	20	14	70	13	13	100	07	01	14

Type of Warts Response						
Type	Total	Improved 100%	Improved with drug	%	Improved with placebo	%
Total cases	104	64	52	81	12	19
V. Vulgaris	39	17	12	70	05	30
V. Plana	20	16	12	75	04	25
V. Plantar	12	10	08	80	02	20
V. Filiform	12	06	06			
V. Genitalis	01	01	01			
Molluscum	20	14	13	93	01	07

### Observations

- The results of active drug group are far better than the placebo group. This again reconfirms the observations made in previous project report that homoeopathic medicines are quite effective in the treatment of warts and Molluscum contagiosum.
- The improvement results of placebo group (19%) in the study under Project 2 is significant as compared to those of 33.4% in the Project 1. This clarifies the doubtful observation of carry over effects of homoeopathic treatment and signifies that probably homoeopathic medicines have no carry over effects in the treatment of warts and Molluscum contagiosum. Hence the effectivity of the indicated medicine can be perceived within few days of its intake.
- Among results of individual medicine. *Thuja* was found most useful drug for warts and *Calcarea carbonicum* for Molluscum contagiosum. The sample sizes of active drug group and placebo group in respect of *Ruta* and *Causticum* are insufficient to comment on the efficacy of these medicines in the treatment of warts.

### Conclusion

The findings of earlier open studies and common belief that homoeopathy has a curative role in the treatment of warts and molluscum contagiosum is re-established in these two studies.

### References

1. Limmer BL, Louis BT. Cryosurgery of plantar wart. J. Am Pod Assoc 1979; 69:713.
2. Davidson MR. Skin curettage and the treatment of plantar verruca. J Am Pod Assoc 1976; 66:331-6.
3. Clinton WL. Verruca, a Dermatologic problem. JAMA 1950, 44: 1361-5.
4. McKnight AG. Assessment of treatment of plantar warts. Ulster Med 1968; 40: 40-53.
5. Bersaques JD. Vitamin A acid in the topical treatment of plantar wart. Dermatologica 1975; 150: 369-71.
6. Hudson AL. Treatment of plantar warts with Bleomycin. Arch Derm 1976; 112: 1179.
7. Moorris Brians AP. Hypnotherapy of warts using The Simonton visualization technique. Am J. Clin Hypnosis 1985; 27: 237-40.
8. Sehgal V.N. Thuja, an antibacterial agent in the management of wart. Indian J Derm and Ven 1967; 33: 37-39.
9. Chand DH, Verucca. Br. Hom J 1986; 175: 18-26.
10. Boericke W. Pocket Manual of Homoeopathic Materia Medica with Repertory. Pp. 55-918. New Delhi: B. Jain 1987