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# Efficacy of homoeopathic treatment for diabetic distal symmetric polyneuropathy: A multicentric randomised double-blind placebo-controlled clinical trial

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## ABSTRACT

**Background:** There are limitations in the management of Diabetic Distal Symmetric Polyneuropathy (DDSP) in conventional system but in Homoeopathy the research studies have shown positive results. These studies were not robust enough to prove the efficacy of individualized homoeopathy, thus this protocol has been developed to assess the efficacy of these individualized homoeopathic drugs in this disease.
**Material and Methods:** It shall be a double blind randomised placebo controlled clinical trial. On the basis of earlier observational studies and repertorial anamnesis of DDSP symptoms, 15 homoeopathic medicines have been identified. The validated scales are being used for evaluating the outcomes post-intervention. The primary outcome is change in Neuropathy Total Symptom Score-6 (NTSS-6) from baseline to 12 months. The secondary outcomes include the changes in HbA1c, peripheral nerve conduction test, World Health Organization Quality Of Life BREF (WHOQOL-BREF) and Diabetic Neuropathy Examination (DNE) Score at 12 months post intervention.
**Discussion:** Results from this trial will help to construct a strategy for treating the patients with DDSP and for improving the quality of life of diabetic patients.
**Trial Registration:** Clinical Trial Registry - India: CTRI/2013/07/003818.

**Keywords:** Clinical trial, Diabetes mellitus, Homoeopathy, Medicine, Polyneuropathy

## BACKGROUND

Diabetic neuropathy is defined as the presence of symptoms and/or signs of peripheral nerve dysfunction in a patient with diabetes, after the exclusion of other causes. In course of diabetes, some 20-90% of individuals eventually develop diabetic neuropathy.[1] Diabetes affects approximately 246 million people worldwide out after and of these about 20-30 million people worldwide are affected by symptomatic diabetic neuropathy. More than 80% of patients with clinical diabetic neuropathy have a distal symmetrical form of the disorder.[2,3]

Blood sugar levels and duration of the disease are the main risk factors for development of this disease.[4,5] So, it is essential to develop a strategy to stop the progression of this disabling condition to the extent possible.

The conventional treatment includes non-steroidal anti-inflammatory drugs (NSAIDs), anti-depressants, etc., which are having side effects and are even contraindicated in certain conditions.[1] There are no

specific guidelines for painful diabetic neuropathy and many patients remain untreated or undertreated.[6]

An observational comparative study by R. Pomposelli *et al*. on forty five type 2 diabetic patients with polyneuropathy showed substantial stability of the electro-neuro-physiological values and nerve conduction test, blood pressure and body weight in both groups. A slight decrease of fasting blood glucose, glycated haemoglobin, improvement in QOL scores, decrease in usage and per capita cost of allopathic drugs were found in homoeopathic group.[7] A prospective multi-centric open clinical trial carried out by CCRH also showed statistical improvement in all the symptoms of DDSP with the usage of 15 homoeopathic medicines on individual symptoms.[8]

Considering the positive outcome of these studies which are generally underpowered, this protocol has been developed to initiate new study with proper rigor and sample size. This document is a clinical research protocol designed for human research study which will be strictly adhered to while undertaking the trial. This study shall be conducted according to Declaration of Helsinki[9] and Good Clinical Practice in India.

## MATERIAL AND METHODS

### Study Aims

#### Primary

To evaluate the efficacy of homoeopathic treatment using pre-identified medicines in the management of DDSP.

#### Secondary

- To assess the change in QOL of patients using WHO QOL BREF questionnaire
- To assess the change in diabetic neuropathy examination (DNE) score post intervention.

### Study Design and Setting

It shall be a double-blind randomised placebo-control clinical trial in which patients will be enrolled for 6 months or till sample size is complete whichever is earlier + one year of follow up. The patients will be enrolled at the outpatient department (OPD) of six research centres spread all over India. These Institutes/Units have been selected for carrying out the research study keeping in view prevalence of the disease, adequacy of the manpower, facilities of laboratory investigations and the willingness of the research personnel at the centres.

Following validated scales are being used during this trial at different times during data collection:

#### Diabetic neuropathy symptom score (DNS score)

It is a four-item validated symptom score, with high predictive value to screen for peripheral neuropathy (PNP) in diabetes.[10,11]

#### Diabetic neuropathy examination score (DNE score)

The DNE score is a sensitive and validated hierarchical physical examination scoring system, which contains two items concerning muscle strength, one concerning reflexes and five concerning sensation, for a total of eight items.[12,13]

#### Neuropathy Total Symptom Score (NTSS-6) - Healthcare Professional administered version

The evaluating healthcare professional will complete a score of frequency times intensity by asking patients about their symptoms of deep aching pain, burning pain, and prickling sensation as well as numbness in their lower extremities.[14]

#### WHO QOL-BREF

This is a questionnaire asked from the patient as how he/she feels about their QOL, health or other areas of life within last 4 weeks. The questions along with the options will be read out by the investigator or read by the patient himself/herself and appropriate answer will be marked at three months interval.[15]

The risk group patients shall be screened with DNS score and other laboratory parameters. Consent will be obtained from the patients during screening. The subjects qualifying inclusion criteria shall be subjected to intervention. The cases have been randomised to receive either of interventions, that is homoeopathic medicine or placebo. 15 homoeopathic medicines have been identified on the basis of earlier observational studies and repertorial anamnesis of DDSP symptoms. These medicines have been blinded at the headquarter level and have been sent to the centres to be prescribed as per the randomisation. The process of randomization, investigation and follow up has been detailed in Figure 1.

As the study is double blind, it has been ensured that the investigator prescribes the intervention as per the randomisation code provided to him and the pharmacist has sole access to medication to be dispensed as per the instructions.

Unblinding of the study will be done only after the study is completed in all the centres and the final data will be analysed statistically by the team

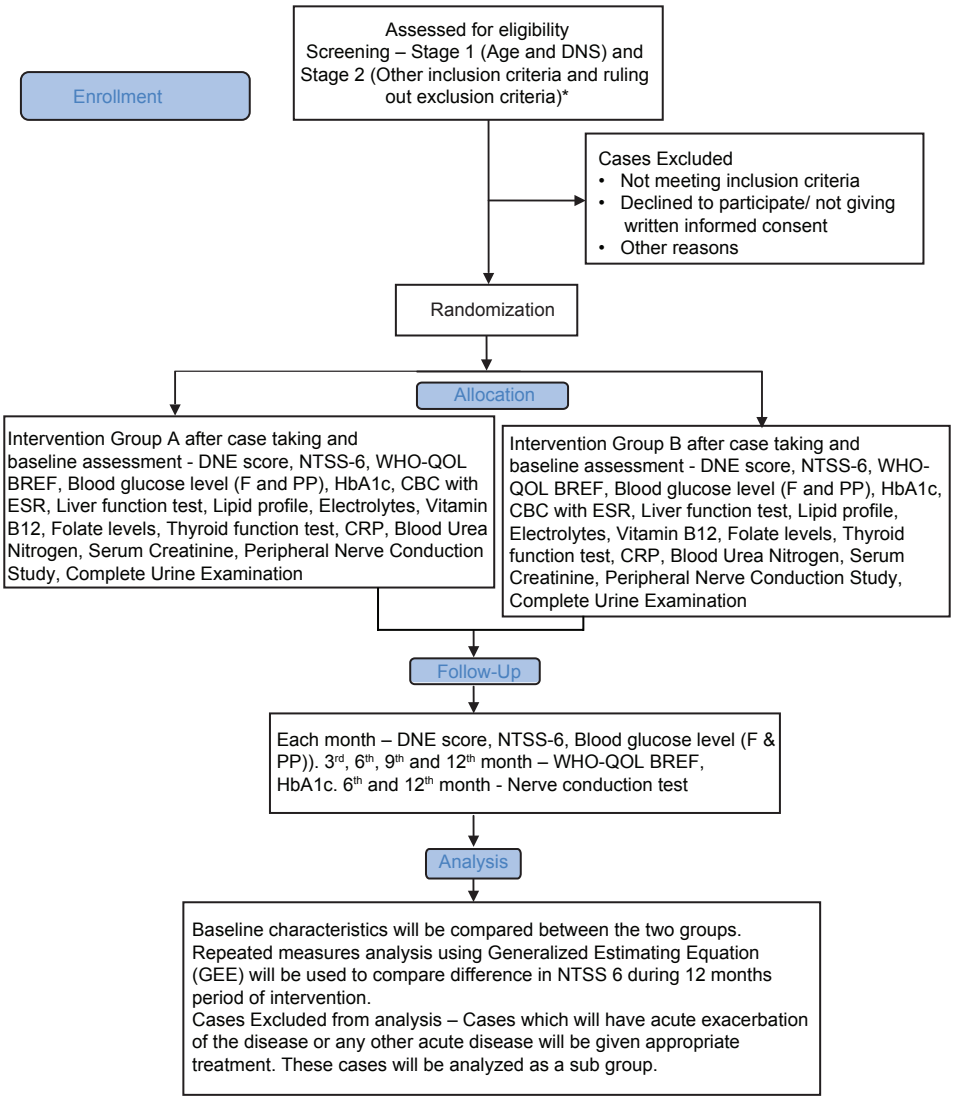


**Figure 1:** Consort flow diagram
*See Study Eligibility Criteria

at headquarters. However, in case of any serious adverse event, the particular participant will be unblinded after reporting to the co-ordinator/ co-co-ordinator as early as possible and at CCRH headquarters within 24 working hours by phone or fax followed by written narration of the event within 48 hours. The same will be mentioned in the Case Recording Format of the patient at the centre.

## Ethical Approval

The intervention drugs are known homoeopathic pharmacopoeial preparations. The study has been approved by the Ethical Committee vide letter 1-169/2011-12/CCRH/CR/DDSP/858/July 2013.

## Sample Size

The sample size was calculated with NTSS-6 as the primary outcome variable. Assuming mean ± SD NTSS-6 during 12 months period post-intervention in the control arm as 10 ± 4 and in the intervention arm 8 ± 4, to detect this difference with 95% confidence level, 90% power, 10 post-intervention measurements, and correlation in repeated value of NTSS-6 as 0.7, we would require 30 evaluable patients in each group. Considering some loss to follow up, at least 42 patients in each group will be taken. However, sample size calculation will be revisited based on the data accumulated by 6 months time.

## Study Eligibility Criteria*

Eligible participants comprise males and females, aged 30-70 years, suffering from type 2 diabetes but stable with allopathic treatment for past 3 months. Patients will be selected for the study as per the detailed screening, which includes the

signs (DNE score ≥3), symptoms (DNS score ≥1), abnormal nerve conduction test, HbA1c ≤8%, controlled hypertension and those who provide the written informed consent.

Participants shall be excluded if they have diabetic mononeuropathy, diabetic polyradiculopathy, diabetic amyotrophy, diabetic autonomic neuropathy, abnormalities of gait, development of typical Charcot's joints, particularly in the feet, loss of arch with multiple fractures of tarsal bones, wrist and/or foot drop, paralysis of III, IV or VI cranial nerves, myocardial infarction less than 6 months, unstable angina, neuropathy due to other causes, for example vitamin B12 deficiency, alcohol addiction or dependence, cases presenting with long-term complication of diabetes such as severe retinopathy, severe renal involvement or with history of recurrent acute complications like hypoglycaemia, ketoacidosis, etc., cases with other systemic diseases like cardiovascular, endocrinal diseases like thyroid dysfunction or systemic infections or on other treatment therapies (Except for hypertensive and dyslipidaemic patients on standard care).

## Data Collection

Data collection shall start with the screening procedures, which involve a two stage screening as mentioned below:

## Stage I

### 'Preliminary verbal screening'

OPD doctor looks for the presence of signs and symptoms (DNS score) and/or diagnosed cases of diabetic polyneuropathy. Screened subjects will be sent to the investigating officer who will perform detailed screening after taking the written informed consent from the patient for taking part in the study.

## Stage II

### Detailed screening

The investigator and the consultant from conventional system will examine the patient and advise for relevant investigations to confirm fulfilment of inclusion criteria and rule out the factors mentioned in the exclusion criteria to enrol the patient in the study.

## Randomisation

All enrolled patients are allocated the intervention as per the Block randomisation. This is done for each centre separately. Random generated codes are made available from computer-based software, RALLOC. Enrolment number of the patient is used for the purpose for randomisation. Initial randomisation is maintained for all follow up visits.

The measurement domains, tools and time points at which data are collected are shown in Table 1.

## Data Management

The information of all patients screened and enrolled is to be recorded. The case history of each case is to be recorded in the Case Recording Format and the relevant annexure pertaining to base line assessment, NTSS-6, DNE, WHOQOL BREF, Acute Phase Information Sheet, Adverse Event Reporting Form and details of medicine dispensing are to be filled and maintained.

The patients who stop taking the allopathic medicines or stop taking the intervention on his/her own, will be considered under as Protocol Violation. So these patients will not be considered for analysis 'as per protocol'. Similarly the cases that suffer from any intercurrent/concurrent or acute complaint and are subjected to acute homoeopathic medicine or conventional therapy will not be considered for analysis 'as per protocol'. Such cases will be considered for sub-group analysis and also can be considered for analysis under the principle for 'intention to treat'.

## Study Arms

### Intervention arm

The homoeopathic medicines shortlisted are to be prescribed to the patients enrolled in this group. The shortlisted medicines are: *Arsenic alb*, *Calcarea carb*, *Carbo veg, Conium mac*, *Kali carbonica, Lycopodium*, *Phosphorus, Pulsatilla, Plumbum, Mercurius, Sulphur*, *Phosphoric acid*, *Natrum muraticum*, *Nitric acid* and *Zincum met*. The medicine is to be selected through a process of constructing the symptom totality for the case followed by repertorisation and consulting the homoeopathic materia medica.

### Control arm

Patients to be given placebo in this group, which is prepared with same liquid solvent as used for preparation of medicine but without any medicinal substance. The placebo is identical to the medicine dispensed to the other group.

## Treatment and Follow-up

In both the groups the patients will continue with the standard care as per the conventional system of medicine, which will be monitored by the consultant

**Table 1: Data collection at baseline, 3, 6 and 12 months**

| Variable/months | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Socio-demographic measures | During case taking | | | | | | | | | | | |
| Age | | | | | | | | | | | | |
| Sex | | | | | | | | | | | | |
| Height | | | | | | | | | | | | |
| Weight (Wt.) | | Wt. | Wt. | Wt. | Wt. | Wt. | Wt. | Wt. | Wt. | Wt. | Wt. | Wt. |
| BMI | | BMI | BMI | BMI | BMI | BMI | BMI | BMI | BMI | BMI | BMI | BMI |
| Medical history | | | | | | | | | | | | |
| Family history of DM | During case taking | | | | | | | | | | | |
| Duration of illness | √ | | | | | | | | | | | |
| DNE | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ |
| NTSS-6 | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ |
| Biochemical measures | | | | | | | | | | | | |
| Blood glucose level-fasting | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ |
| Post-prandial | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ |
| HbA1c | √ | | √ | | | √ | | | √ | | | √ |
| CBC with ESR | √ | | | | | | | | | | | |
| Liver function test-total bilirubin | √ | | | | | | | | | | | |
| Direct bilirubin | √ | | | | | | | | | | | |
| ALT | √ | | | | | | | | | | | |
| AST | √ | | | | | | | | | | | |
| ALP | √ | | | | | | | | | | | |
| Total protein | √ | | | | | | | | | | | |
| Albumin | √ | | | | | | | | | | | |
| Globulin | √ | | | | | | | | | | | |
| A:G | √ | | | | | | | | | | | |
| Lipid profile– | √ | | | | | | | | | | | |
| Total cholesterol | √ | | | | | | | | | | | |
| Tryglycerides | √ | | | | | | | | | | | |
| HDL | √ | | | | | | | | | | | |
| LDL | √ | | | | | | | | | | | |
| VLDL | √ | | | | | | | | | | | |
| Electrolytes– | √ | | | | | | | | | | | |
| $Na^{+}$ | √ | | | | | | | | | | | |
| $K^{+}$ | √ | | | | | | | | | | | |
| $Ca^{++}$ | √ | | | | | | | | | | | |
| Vitamin B12 | √ | | | | | | | | | | | |
| Folate levels | √ | | | | | | | | | | | |
| Thyroid function test– | √ | | | | | | | | | | | |
| TSH | √ | | | | | | | | | | | |
| Free T3 | √ | | | | | | | | | | | |
| Free T4 | √ | | | | | | | | | | | |
| C reactive protein | √ | | | | | | | | | | | |
| Blood urea nitrogen | √ | | | | | | | | | | | |
| Serum creatinine | √ | | | | | | | | | | | |
| Other diagnostics | | | | | | | | | | | | |
| Peripheral nerve conduction study | √ | | | | | √ | | | | | | √ |
| Urine examination– | √ | | | | | | | | | | | |
| Routine | | | | | | √ | | | | | | √ |
| Culture | | | | | | √ | | | | | | √ |
| Psychosocial aspect | | | | | | | | | | | | |
| Health-related quality of life (WHO QOL BREF) | √ | | √ | | | √ | | | √ | | | √ |

**Table 2: Potency, dosage and repetition of the medicine**

| Potency | Dosage and duration | NTSS-6 reduced by 5-25% (after one month) | NTSS-6 not reduced by 5-25% (after one month) | |
|---|---|---|---|---|
| | | | Same symptoms | Change in symptoms |
| 6C | 3 doses/day for 15 days. Placebo for 15 days | Repeat same potency with same dosage and repetition till improvement continues | Go to next higher potency | If medicine indicated from the pre-identified medicines prescribe that, else treat in general OPD |
| 30C | 2 doses/day for 15 days. Placebo for 15 days | Repeat same potency with same dosage and repetition till improvement continues | Go to next higher potency | If medicine indicated from the pre-identified medicines prescribe that, else treat in general OPD |
| 200C | 1 dose/day for 15 days. Placebo for 15 days | Repeat same potency with same dosage and repetition till improvement continues | Go to next higher potency | If medicine indicated from the pre-identified medicines prescribe that, else treat in general OPD |
| 1M | 1 dose each at 15 days interval. Placebo for 15 days each between the medicine doses | Repeat same potency with same dosage and repetition till improvement continues | Go to next higher potency | If medicine indicated from the pre-identified medicines prescribe that, else treat in general OPD |

Note: If there is no improvement after giving 1M then the symptom totality is to be reconsidered and if the same medicine is indicated and investigator feels that there is a need to prescribe 10M of the same medicine, he will contact the co-ordinator at the headquarters. OPD: Outpatient department, NTSS: Neuropathy total symptom score

attached at each centre for the study. Homoeopathic medicines will be prescribed serially beginning with 6C, followed by 30C, 200C and 1M as per the need of the case. As this is a pathological condition and is affecting the nervous system the starting potency has been kept low with frequent repetition.

### Dosage and Repetition

The dosage of the medicine to be administered and its repetition are mentioned in Table 2.

### Follow-up Assessment

It shall be done considering the following parameters:

a. Any change in the score
b. Any change in prescribing totality
c. General well being of patient
d. Any other change or observation in the case
e. Any change in laboratory reports.

### Acute Phase

In case of acute exacerbation of diabetic neuropathy or any other acute disease arising during the course of treatment, prescription will be changed and selection of the medicine will be based on the characteristic attributes of the chronic phase. Investigators will select a new medicine as per the acute totality of the case or refer for conventional treatment as the case may be. Previously prescribed medicines/placebo are to be discontinued till acute phase is over. Record to be maintained in follow up sheet for acute phase.

### Outcome Measures

The primary outcome measure is change in NTSS-6 from baseline to 12 months. The secondary outcomes include the changes in DNE score, HbA1c, Peripheral nerve conduction test and WHO QOL BREF between the groups post-intervention.

## TREATMENT ASSESSMENT

Assessment of improvement will be done after all the potencies (6C, 30C, 200C and 1M) of the selected medicine have been used; clinically improved patients will be put on periodic observation till they complete one year follow up for final assessment. A patient will be labelled as failure if the complaints persist or worsen after the medicine has been tried in all potencies during the period of one year.

## DATA ANALYSIS

### Statistical Method

Data obtained from all the study centres would be verified and analysed using following statistical methods:

Baseline characteristics will be compared between the two groups. Repeated measures analysis using Generalised Estimating Equation (GEE) will be used to compare difference in NTSS-6 during 12 months intervention period. Following would be considered as potential confounders in diabetes mellitus – hereditary factor, diet, smoking, obesity, stress, etc., In case there is imbalance in the distribution of these potential confounders between the two treatment arms, multivariate analysis will be used to adjust for the effect of these confounders on the effect size. For the primary outcome and each of the secondary outcomes, both per protocol and intention to treat analysis will be done. Effect

size and 95% confidence interval will be computed. O'Brien and Fleming Stopping Rule will be used for one interim analysis at 6 months and final analysis at 18 months. After the final analysis group code will be broken. SPSS software will be used for data analysis.

## DISCUSSION

The results which will be obtained from the study will be compared with the previous studies. It is hoped that the outcome of the study will be useful to the profession in general and researchers in particular.

## TRIAL STATUS

The trial is currently in the recruitment phase.

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**पृष्ठभूमि :** पारंपरिक प्रणाली में मधुमेह दूरस्थ सममितीय पोलीन्योरोपैथी के प्रबंधन में सीमाएँ है लेकिन होम्योपैथी अनुसंधान अध्ययनों ने सकारात्मक परिणाम दिखाये हैं। ये अध्ययन व्यक्तिगत होम्योपैथी की प्रभावकारिता को सिद्ध करने के लिए पर्याप्त नहीं थे, इसलिए इस रोग में व्यक्तिगत होम्योपैथी दवाओं की प्रभावकारिता का आकलन करने के लिए इस प्रोटोकॉल को विकसित किया गया।

**सामग्री एवं विधियाँ:** यह चिकित्सीय परीक्षण डबल ब्लाईण्ड यादृच्छिक प्लासिबो नियंत्रित किया जायेगा। मधुमेह दूरस्थ सममितीय पोलीन्योरोपैथी लक्षणों के पहले पर्वेक्षणीय अध्ययनों और रेपरटोरियल स्मृति के आधार पर 15 होम्योपैथी औषधियों की पहचान की गई है। मान्य पैमानों को हस्तक्षेप के बाद प्राप्त परिणामों के मूल्यांकन लिए इस्तेमाल किया जा रहा है। प्राथमिक परिणाम आधार रेखा से 12 महीने बाद न्येरोपैथी में कुल लक्षण स्कोर–6 (एनटीएसएस–6) पैमाने में परिवर्तन का मल्यांकन है। द्वितीय परिणाम एचबीए1सी, परिधीय तंत्रिका चालन परीक्षण बीआरइएफ जीवन की विश्व स्वास्थ्य संगठन गुणवत्ता (डब्लूएचओक्यूओएल–बीआरइएफ) और मधुमेह तंत्रिका परीक्षण (डीएनई) स्कोर सहित आधार रेखा से 12 महीने बाद प्राप्त हुए परिवर्तन का मूल्यांकन है।

**चर्चा :** इस परीक्षण का परिणाम मधुमेह दूरस्थ सममितीय पोलीन्योरोपैथी और मधुमेह पीड़ित मरीजों की जीवन गुणवत्ता में सुधार के साथ रोगियों के उपचार के लिए रणनितियां बनाने में मदद करेगा।

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