

## Clinical Trial Details (PDF Generation Date :- Wed, 10 Aug 2022 16:04:04 GMT)

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|---|---|
| **CTRI Number** | CTRI/2010/091/000418 [Registered on: 15/09/2010] - |
| **Last Modified On** | |
| **Post Graduate Thesis** | |
| **Type of Trial** | |
| **Type of Study** | |
| **Study Design** | Single Arm Study |
| **Public Title of Study** | A clinical trial of herbal compound MA-305 in patients with mild to moderate hypertension: A Pilot Study. |
| **Scientific Title of Study** | A clinical trial of herbal compound MA-305 in patients with mild to moderate hypertension: A Pilot Study. |

**Secondary IDs if Any**

| Secondary ID | Identifier |
|---|---|
| NIL | NIL |

**Details of Principal Investigator or overall Trial Coordinator (multi-center study)**

| Details of Principal Investigator | |
|---|---|
| **Name** | Dr.Randeep Guleria, MD, DM, MNAMS |
| **Designation** | |
| **Affiliation** | |
| **Address** | Professor , Department of Medicine, All India Institute of Medical Sciences, New Delhi ? 110029<br>New Delhi<br>DELHI<br>110029<br>India |
| **Phone** | 011-26593676 (O),011-26198654, (R) |
| **Fax** | 91-11-2658866, 26589732 |
| **Email** | randeepg@hotmail.com |

**Details Contact Person (Scientific Query)**

| Details Contact Person (Scientific Query) | |
|---|---|
| **Name** | Dr.Randeep Guleria, MD, DM, MNAMS |
| **Designation** | |
| **Affiliation** | |
| **Address** | Professor , Department of Medicine, All India Institute of Medical Sciences, New Delhi ? 110029<br>New Delhi<br>DELHI<br>110029<br>India |
| **Phone** | 011-26593676 (O),011-26198654, (R) |
| **Fax** | 91-11-2658866, 26589732 |
| **Email** | randeepg@hotmail.com |

**Details Contact Person (Public Query)**

| Details Contact Person (Public Query) | |
|---|---|
| **Name** | Mr. S. M. Bhushan,M.pharmacology and M.Pharmaceutics,Dip. bact<br>Director Reseach |
| **Designation** | |
| **Affiliation** | |
| **Address** | Mr. S. M. Bhushan Director Research, Maharishi Ayurveda Products Pvt. Ltd., A-14, M.C.I.E., Mathura Road, New Delhi ? 110 044<br>New Delhi<br>DELHI<br>110044<br>India |

| | |
|---|---|
| **Phone** | 011-26959040,09811158589 |
| **Fax** | Phone & TeleFax: 011-26959040 |
| **Email** | maharishibhushanrnd@yahoo.co.in |

**Source of Monetary or Material Support**

| Source of Monetary or Material Support |
|---|
| > Maharishi Ayurveda Products Pvt. Ltd., A-14, M.C.I.E., Mathura Road, New Delhi ? 110 044. Phone & TeleFax: 011-26959040, Mob. 9811158589 |

**Primary Sponsor**

| Primary Sponsor Details | |
|---|---|
| **Name** | Sh. Anand Shrivastava Chairman & MD, Maharishi Ayurveda Products Pvt. Ltd., A-14, M.C.I.E., Mathura Road, New Delhi ? 110 044. Phone : 011-26959401, 403. |
| **Address** | |
| **Type of Sponsor** | |

**Details of Secondary Sponsor**

| Name | Address |
|---|---|
| NIL | |

**Countries of Recruitment**

| List of Countries |
|---|
| India |

**Sites of Study**

| Name of Principal Investigator | Name of Site | Site Address | Phone/Fax/Email |
|---|---|---|---|
| Dr.Randeep Guleria, MD, DM, MNAMS, Professor of Medicine | Department of Medicine, All India Institute of Medical Sciences, New Delhi | Department of Medicine, All India Institute of Medical Sciences, New Delhi ,-110029 New Delhi DELHI | 011-26593676 (O),011-26198654, (R) 91-11-2658866, 26589732 randeepg@hotmail.com |

**Details of Ethics Committee**

| Name of Committee | Approval Status | Date of Approval | Is Independent Ethics Committee? |
|---|---|---|---|
| Ethics Committee of All India Institute of Medical Sciences. | Approved | No Date Specified | Not Available |

**Regulatory Clearance Status from DCGI**

| Status | Date |
|---|---|
| Not Applicable | No Date Specified |

**Health Condition / Problems Studied**

| Health Type | Condition |
|---|---|
| | Mild to Moderate Hypertension. |

**Intervention / Comparator Agent**

| Type | Name | Details |
|---|---|---|
| Intervention | Cardimap (MA 305 | A herbal formulation developed by Maharishi Ayurveda to arrest, abate and control hypertension. It is presented in the form of tablet and contains the following herbal ingredients. 1 Rauwolfia serpentina ? (Sarpagndha) 2 Nardostachys jatamansi ? (Jatamansi) 3 Bacopa monnieri ? (Brahmi) 4 Convolvulus pluricaulis - (Shankpushpi) 5 Piper longum ? (Pippali) Two Tablets of 500mg each twice a day with water. |
| Comparator Agent | No Comparator agent to be used | None |

**Inclusion Criteria**



| Inclusion Criteria | |
|---|---|
| **Age From** | |
| **Age To** | |
| **Gender** | |
| **Details** | 1.. Patients who are willing to participate in the study. `2 . Aged 18 to 70 yrs. `3. Primary hypertensive patients. `4. Patients with pre hypert ensive ( SBP: 120-130, DBP: 80-89) and stage 1( SBP:140-159, DBP: 90-99) (According to JNC 7 criteria). ``5. patients with stable blood pressure and with no significant change in their therapy over the last 4 ``weeks prior to entry into the study. |

**Exclusion Criteria**

| Exclusion Criteria | |
|---|---|
| **Details** | (a) Patients unwilling to participate. (b) Pregnancy and breast-feeding. (c) Concomitant severe diseases. (d) Uncontrolled hypertension. |

| | |
|---|---|
| **Method of Generating Random Sequence** | Not Applicable |
| **Method of Concealment** | Not Applicable |
| **Blinding/Masking** | Not Applicable |

**Primary Outcome**

| Outcome | Timepoints |
|---|---|
| The aim of study is to evaluate the efficacy and tolerability of herbal compound MA ?305 in patients with mild to moderate hypertension. | |

**Secondary Outcome**

| Outcome | Timepoints |
|---|---|
| NO | |

| | |
|---|---|
| **Target Sample Size** | **Total Sample Size=**50<br>**Sample Size from India=**<br>**Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials<br>**Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials |
| **Phase of Trial** | Phase 3/ Phase 4 |
| **Date of First Enrollment (India)** | No Date Specified |
| **Date of First Enrollment (Global)** | 01/09/2010 |
| **Estimated Duration of Trial** | **Years=**2<br>**Months=**0<br>**Days=**0 |
| **Recruitment Status of Trial (Global)** | Open to Recruitment |
| **Recruitment Status of Trial (India)** | |
| **Publication Details** | |
| **Brief Summary** | The aim of the study is to evaluate the safety efficacy & tolerability of herbal compound Cardimap (MA-305) in patients with mild to moderate hypertension. Patients with mild to moderate hypertension who meet the study criteria will be included after taking a written informed consent. During the initial 2- weeks baseline period and at the end of 12- weeks of active therapy, all basic investigations including haemogram, biochemistry will be done. Patient will be clinically reviewed after every 4 weeks. Blood pressure will be monitored in supine, sitting and standing position. In baseline period when blood pressure becomes stable, patients will be given the study medicine along with antihypertensive drugs, which have been prescribed earlier. All antihypertensive drugs will be continued and the patient will be regularly monitered during the study period. The trial medicine will be stopped after 12- weeks. Patients will be followed up for another 2-weeks without medicine. Side effects if any will be recorded in the case record form. After completion of the study, we will evaluate the result with appropriate statistical analysis. |