### Clinical Trial Details

**CTRI Number**: CTRI/2012/04/002583 [Registered on: 18/04/2012] - Trial Registered Retrospectively

**Last Modified On**: 21/03/2012

**Post Graduate Thesis**: Yes

**Type of Trial**: Interventional

**Type of Study**: Ayurveda

**Study Design**: Randomized, Parallel Group Trial

**Public Title of Study**: A clinical and experimental study to compare the four types of virechana karma (Purgation Therapy) i.e Anulomana-By Haritaki, Sramsana-By Aragwadha, Bhedana-By Katuki,Rechana-By Trivrit and their efficacy in the management of Ekakushtha (Psoriasis).

**Scientific Title of Study**: A Clinico-Experimental Study on Four Types Of Virechana Karma in Ekakushtha (Psoriasis)

**Secondary IDs if Any**

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Dr Vikram Kumar</th>
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<tbody>
<tr>
<td>Designation</td>
<td>Ph D Scholar</td>
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<td>Affiliation</td>
<td>Institute for Post Graduate Teaching &amp; Research in Ayurveda</td>
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<td>Address</td>
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</tr>
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**Details Contact Person (Scientific Query)**

<table>
<thead>
<tr>
<th>Name</th>
<th>Dr Anup B Thakar</th>
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<tbody>
<tr>
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<td>Email</td>
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**Details Contact Person (Public Query)**

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<tr>
<td>Source of Monetary or Material Support</td>
<td>Institute for Post Graduate Teaching &amp; Research in Ayurveda, Gujarat Ayurved University Jamnagar-361008.</td>
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| Primary Sponsor                      | Name: IPGTRA  
Address: Institute for Post Graduate Teaching & Research in Ayurveda, Gujarat Ayurved University Jamnagar-361008.  
Type of Sponsor: Research institution and hospital |
| Details of Secondary Sponsor         | Name: NIL  
Address: NIL |
| Countries of Recruitment             | India |
| Sites of Study                       | Name of Principal Investigator: Dr Vikram Kumar  
Name of Site: Department of Panchakarma, IPG & RA Hospital Jamnagar  
Site Address: Institute for Post Graduate Teaching & Research in Ayurveda, Gujarat Ayurved University Jamnagar-361008.  
Phone/Fax/Email: 919574937714  
vikramkumar83@gmail.com |
| Details of Ethics Committee          | Name of Committee: Institutional Ethics Committee IPG & RA Jamnagar.  
Approval Status: Approved  
Date of Approval: 15/12/2010  
Is Independent Ethics Committee?: No |
| Regulatory Clearance Status from DCGI | Status: Not Applicable  
Date: No Date Specified |
| Health Condition / Problems Studied  | Health Type: Patients  
Condition: Patients suffering from psoriasis |
| Intervention / Comparator Agent      | Type: Intervention  
Name: Terminalia chebula Retz  
Details: About 25-50gms of Terminalia chebula Retz fruit coarse powder is taken and decoction is prepared. About 150-250ml is administered orally once for Virechana (purgation). Duration: 15-20 days.  
Type: Comparator Agent  
Name: Cassia fistula Linn  
Details: About 25-50gms of Cassia fistula Linn fruit pulp is taken and hot effusion is prepared. About 150-250ml is administered orally once for Virechana (purgation). Duration: 15-20 days.  
Type: Comparator Agent  
Name: Picrorhiza kurroa Royle ex Benth  
Details: About 10-30gms of Picrorhiza kurroa Royle ex Benth rhizome coarse powder is taken and... |
### Comparator Agent

| Operculina turpethum Linn | About 10-30gms of Operculina turpethum Linn root coarse powder is taken and decoction is prepared. About 150-250ml is administered orally once for Virechana (purgation). Duration: 15-20 days. |

### Inclusion Criteria

| Age From | 17.00 Year(s) |
| Age To | 60.00 Year(s) |
| Gender | Both |
| Details | 1. Patients with all forms of Psoriasis who are clinically fit to undergo Virechana procedure. 2. Age - 17 to 60 years 3. Sex - Both sexes 4. Patients having Madhyma Koshtha |

### Exclusion Criteria


### Method of Generating Random Sequence

- Coin toss, Lottery, toss of dice, shuffling cards etc
- Not Applicable

### Method of Concealment

- Participant Blinded

### Primary Outcome

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Timepoints</th>
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<tbody>
<tr>
<td>Assessment of Virechana - Based on Vaigiki shuddhi, Maniki shuddhi, Laingiki shuddhi and Antiki shuddhi. - Time of administration of Virechana drug &amp; time of onset of first vega. - Total duration of Virechana. - Effect of four types of Virechana on Hematological and bio-chemical parameters.</td>
<td>Assessment will be done during the time of Virechana.</td>
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### Secondary Outcome

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<tr>
<td>1. Improvements in signs and symptoms of Psoriasis. 2. Improvements in Dermatology Life Quality Index. 3. Improvements in Psoriasis Area Severity Index (PASI) score.</td>
<td>Assessments will be done before and after treatment and changes will be noted.</td>
</tr>
</tbody>
</table>

### Target Sample Size

| Total Sample Size | 100 |
| Sample Size from India | 100 |
**Phase of Trial**  
Phase 1/ Phase 2

**Date of First Enrollment (India)**  
18/07/2011

**Date of First Enrollment (Global)**  
No Date Specified

**Estimated Duration of Trial**  
Years=1  
Months=4  
Days=0

**Recruitment Status of Trial (Global)**  
Not Applicable

**Recruitment Status of Trial (India)**  
Open to Recruitment

**Publication Details**

**Brief Summary**

The purpose of the study is
1. To compare the four types of *Virechana Karma* (Purgation therapy) i.e *Anulomana, Sramsana, Bhedana and Rechana* in patients of *Ekakushtha* (Psoriasis).
2. To compare the efficacy of four types of *Virechana Karma* on *Ekakushtha* (Psoriasis).

**Method of research:** Patients of psoriasis will be selected based on inclusion & exclusion criteria from O.P.D & I.P.D of I.P.G.T & R.A Hospital, Jamnagar, irrespective of religion, sex, occupation, cast etc. They will be randomly divided into 4 groups, Group A (*Anulomana* group), Group B (*Sramsana* group), Group C (*Bhedana* group) and Group D (*Rechana* group).

**Interventions**

**Group A**

Deepana & Pachana with *Trikatu Choorna* 2gm b.d for 2 days.

Snehapana with *Murchita goghrita* till samyak snigdha lakshanas

Abhyanga & Ooshmasweda for 3 days

Virechana with *Anulomana drug* (*Hareetaki-Terminalia chebula Retz*)

Samsarjana krama.

**Group B**

Deepana & Pachana *Trikatu Choorna* 2gm b.d for 2 days

Snehapana with *Murchita goghrita* till samyak snigdha lakshanas

Abhyanga & Ooshmasweda for 3 days

Virechana with *Sramsana drug* (*Aragwadha-Cassia fistula Linn*)
Samsarjana krama.

Group C

Deepana & Pachana Trikatu Choorna 2gm b.d for 2 days
Snehapana with Murchita goghrita till samyak snigdha lakshanas
Abhyanga & Ooshmasweda for 3 days
Virechana with Bhedana drug (Katuki-Picrorhiza kurroa Royle ex Benth)
Samsarjana krama.

Group D

Deepana & Pachana Trikatu Choorna 2gm b.d for 2 days
Snehapana with Murchita goghrita till samyak snigdha lakshanas
Abhyanga & Ooshmasweda for 3 days
Virechana with Rechana drug (Trivriti-Operculina turpethum Linn)
Samsarjana krama.

Selection of Drug:

Trikatu choorna for Deepana & Pachana
Murchita goghrita for snehapana.

Murchita tila taila for abhyanga

Haritaki (Terminalia chebula Retz) fruit – for Anulomana
Aragwadha (Cassia fistula Linn) fruit pulp – for Sramsana
Katuki (Picrorhiza kurroa Royle ex Benth) rhizome – for Bhedana
Trivrit (Operculina turpethum Linn) root – for Rechana

Dose:

Haritaki - 25-50gms
Aragwadha – 25 -50gms
**Kwatha (Decoction)** of above drugs will be prepared by the classical method and used for Virechana. *Aragwadh* will be administered in the form of *Phanta* (Hot effusion).

**Duration of study:** 15-20 days

**Laboratory investigations:**

1. Routine Blood, Urine and Stool investigations before & after treatment will be done.
2. Biochemical investigations - Blood Sugar, Lipid profile, Serum Bilirubin, Total Proteins, LFT, RFT, and Serum electrolytes will be done before & after treatment

**Assessment Criteria:**

**Assessment of Virechana**

- *Shuddhi* will be assessed based on *Vaigiki shuddhi* (number of vegas), *Maniki shuddhi* (quantity of faeces), *Laingiki shuddhi* (signs and symptoms of proper Virechana) and *Antiki shuddhi* (malanta, pittanta, kaphanta & vatanta).

- Time of administration of *Virechana* drug & time of onset of first vega.

- Total duration of *Virechana*.

- Haematological, urine, stool & biochemical investigations will be done before treatment & after treatment.

**Assessment of response of therapy on Psoriasis**

The improvement provided by different types of *Virechana* will be assessed on the basis of relief in signs & symptoms. All the signs & symptoms will be assigned scores depending upon their severity to assess the effect objectively.