Report Title: A STUDY TO INVESTIGATE THE EFFECT OF INSULIN PLANT HERBAL TEA ON DIABETIC PATIENTS

Period of study: February – June 2016

Project Leader: Dr. Supriya S. Jirge M.Pharm, PhD

Project investigator: Dr. Swapnil S. Dhane

Project leader:
Dr. Supriya S. Jirge
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Indira Institute of Pharmacy
Sadavali
Sangmeshwar- Ratnagiri
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supriyahyam@gmail.com

Project investigator:
Dr. Swapnil S. Dhane
BAMS, DEMS
Dhane Clinic
M. V. Plaza
Near Bank of India
Shivaji Chowk – Devrukh
Sangmeshwar- Ratnagiri

SPONSOR: P.S. Venkatesan
Nethra Organic Farm
Door NO 7, 6th Main Road,
7th Cross Street (Off)
Anna Nagar, Pammal
Chennai: 600075
Tamilnadu
Mob : 9444630429
STUDY SUMMARY

<table>
<thead>
<tr>
<th>TITLE</th>
<th>A study to investigate the effect of insulin plant herbal tea on diabetic patients.</th>
</tr>
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<tbody>
<tr>
<td>Investigational site:</td>
<td>Dhane Clinic, 710, Prituchaya Niwas, Kasarwadi, Sadavali Sangmeshwar - Ratnagiri - 415804</td>
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<td>Investigators:</td>
<td>Dr. Supriya S. Jirge, Asst. Professor, Indira Institute of Pharmacy Sadavali, Sangmeshwar - Ratnagiri</td>
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<td>Sponsor:</td>
<td>Nethra organic farm and Dr. Supriya S. Jirge</td>
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<td>Study period:</td>
<td>Febraury – June 2016</td>
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<td>OBJECTIVES:</td>
<td>To investigate the effect of insulin plant herbal tea in diabetic patients by assessing blood glucose level and blood pressure and blood haemoglobin level (as supporting parameters).</td>
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<td>STUDY PROTOCOL:</td>
<td>A 3 months treatment was carried out for 25 patients having identified either for Type I or Type II diabetes. At Visit 1 the medication history of each patient was recorded and they were screened for their fasting and post-prandial blood glucose level. Patients were treated three times insulin plant herbal tea in a day along with their on-going medication. The subsequent visits were scheduled after two weeks intervals for 90 days. Patients were asked to report any adverse events occur during the treatment period. In total seven times examination of patients were carried out throughout the treatment period. Each time the fasting and post-prandial blood glucose level was recorded along with blood pressure and blood haemoglobin levels.</td>
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<td>SUBJECTS:</td>
<td>Diabetic patients, males and/or females between 30 and 55 years of age were examined, and were informed about the product. No pregnant women or patient below 30 or above 55 were examined.</td>
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<td>PRODUCT TO BE EVALUATED</td>
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<td>SUPPLIED BY</td>
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<td>DURATION OF STUDY</td>
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<td>ENDPOINTS:</td>
<td>1. Adverse events</td>
</tr>
<tr>
<td></td>
<td>2. Physical examination, including weight</td>
</tr>
<tr>
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<td>3. Vital signs: blood glucose level (fasting as well as post-prandial)</td>
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<td>4. Blood pressure, blood haemoglobin</td>
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<td>SAMPLE SIZE:</td>
<td>25 subjects</td>
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1. INTRODUCTION

*Sutherlandia frutescens* (subspecies *microphylla*) (L.) R.Br. is thought to be among the most profound and useful of the medicinal plants in Southern Africa (van Wyk & Gericke, 2000). Tinctures, infusions and decoctions of the leaves and young stems have been widely used in the Cape Region, since the value of this herbal medicine was first discovered by the Khoi, San and Nama people (van Wyk, van Oudshoorn & Gericke, 2000). The traditional Tswana name, Phetola, means, “it changes”. When literally translated, it means that the plant changes the course of many illnesses into favorable outcomes.

Furthermore, the North Sotho name, Lerumo-lamadi, means “the spear for the blood” which refers to the value of *S. frutescens* as a powerful blood-purifier that acts as an all-purpose tonic ([www.astral-natural.com/Africanana.htm](http://www.astral-natural.com/Africanana.htm), appended). Over centuries, this medicinal plant has been indigenously used to treat a variety of conditions including, cancer, viral, bacterial, fungal and parasitic infections, menopausal conditions, varicose veins and hemorrhoids, inflammation, wasting and stress (van Wyk & Gericke, 2000). The medicinal value of the plant has been ascribed to a number of the significant constituents of this phytotherapy, including pinitol, γ-amino butyric acid (GABA), asparagine, sugaryl (SU1) and also L-canaanavine.

Pinitol, which is a known anti-diabetic agent (Davis et al., 2000, Larner et al., 1998), has been isolated from *S. frutescens* leaves. Researchers suggest that pinitol may have clinical application in treating the wasting in cancer and AIDS patients (van Wyk & Gericke, 2000). Pinitol is also claimed to have anti-inflammatory effects (Singh et al. 2001). Some *S. frutescens* subspecies have high levels of concentrations of GABA, an inhibitory neurotransmitter that is assumed to account for their use for anxiety, stress and depression. In *S. frutescens*, asparagine could function as a diuretic by stimulating the kidneys and liver (Rosenthal, 1992). Sugaryl (SU1), a novel triterpenoid glucoside, has only recently been identified, and was used as a marker to select elite *Sutherlandia* chemotypes for the propagation of the plant raw materials ([www.sutherlandia.org/chemistry.html](http://www.sutherlandia.org/chemistry.html), appended).

Canavanine (i.e. L-2-amino-4-(guanidinoxy)butyric acid) is a potent L-arginine antagonist that has documented anti-cancer (Thomas et al., 1987; Rosenthal, 1998; Smith et al., 2003; Ghogomu, 2002, Bence et al., 2002, Bence et al., 2003), apoptosis (Chinkwo et al., 2003, Jang et al., 2002,) as well as anti-infective and anti-oxidant effects (Katarere & Eloff, 2003). It is also thought to affect regulatory and catalytic reactions of arginine metabolism, arginine uptake, formation of structural components and other cellular processes. Canavanine is a potentially deleterious arginine antimetabolite and has been linked to an induction of autoimmune disease e.g. systemic lupus erythematosus (Brown et al. 2001, Farnsworth 1995), but its adverse effects are most likely to occur with very high levels of the compound and/or in presence of low arginine levels and/or in certain predisposed individuals. The level of canavanine in presently used *S. frutescens* preparations is expected to be quite low (around 2.5mg per gram dry powder), but its bioavailability, pharmacokinetics, possible accumulation and effect during chronic use of
the plant has not yet been established. Similarly, this type of information is also not available for the other possible active constituents of this plant medicine.

To our knowledge no clinical study has yet been done on *S. frutescens*. However a pre-clinical study in vervet monkeys (*Chlorocebus aethiops*) was recently done at the Medical Research Council in Tygerberg, South Africa ([www.sahealthinfo.org/traditionalmeds/firststudy.htm](http://www.sahealthinfo.org/traditionalmeds/firststudy.htm), appended). The monkeys were given as much as 9 times the recommended dose (viz. 81.0mg/kg per day p.o. for 3 months), but (compared to control monkeys not receiving the plant material) no clinically significant changes were seen in haematology, blood biochemistry, and physiological variables measured. That is, *S. frutescens* was found to be non-toxic in vervet monkeys.

**Note 1:** While the name *Sutherlandia frutescens* (L.) R.Br. is the adopted scientific name for the plant species referred to in this project, the taxonomy of this species has not been resolved and several names for this taxon are currently in use. This will not impact this study as plant material of this taxon is to be obtained from a reputable commercial supplier, and is from the same chemotype used for the animal toxicity studies. Research on resolving the taxonomy and nomenclature of this taxon could be included in a future project of TICIPS. For the purposes of this Pilot Project the taxa named *Sutherlandia frutescens* (L.) R.Br., *Sutherlandia microphylla* Burch. ex DC., *Sutherlandia frutescens* subspecies *microphylla* (Burch. ex DC.) Moshe & van Wyk *inde*., and *Lessertia frutescens* (L.) P.Goldblatt & J.C.Manning are considered to be taxonomically identical.

**2. STUDY OBJECTIVES**

To investigate the effect of insulin plant herbal tea in diabetic patients by assessing blood glucose level and blood pressure and blood hemoglobin level (as supporting parameters).

**3. STUDY PLAN AND PROCEDURES**

A 3 months treatment was carried out for 25 patients having identified either for Type I or Type II diabetes. At Visit 1 the medication history of each patient was recorded and they were screened for their fasting and post-prandial blood glucose level. Patients were treated three times insulin plant herbal tea in a day along with their on-going medication. The subsequent visits were
scheduled after two weeks intervals for 90 days. Patients were asked to report any adverse events occur during the treatment period. In total seven times examination of patients were carried out throughout the treatment period. Each time the fasting and post-prandial blood glucose level was recorded along with blood pressure and blood haemoglobin levels.

3.2 Investigational Products and Treatments

3.3 Treatment Schedule

Insulin plant herbal tea was supplied in air tight glass container along with a spoon of capacity two gm. It was instructed to consume the decoction of product prepared by adding one spoon full to water and bolied for 5-10 mins. The product was supplied by Nethra organic farm. The re packing of product in a glass container was done by Dr. Supriya S. Jirge at Indira Institute of Pharmacy, Sadavali, Ratnagiri.

3.4. Storage and Accountability

The product was kept in a secure place under adequate storage conditions – protected from moisture and light.

3.5 Allowed medication

Each patient was examined by the physician, Dr. Swapnil S. Dhane and the regular anti-diabetic medications were prescribed as per the need of each patient’s condition along with the insulin plant herbal tea.

3.6 Compliance

All patients were examined twice in a months (after two weeks) at physician’s clinic and the records were maintained with doctor.

3.7 Adverse events

An adverse event is the development of an undesirable medical condition – e.g. symptoms or abnormal results of an investigation - or the deterioration of a pre-existing medical condition (not relevant in this study). AE’s were collected by means of a standard question: “Have you had any health problems since the previous visit?” AE’s were recorded at every visit. The subjects were asked to assess the intensity of the reported Adverse Event according to the following scale:
Mild = awareness of sign or symptom, but easily tolerated
Moderate = discomfort sufficient to cause interference with normal activities
Severe = incapacitating, with inability to perform normal activities.

4. STUDY TIME TABLE AND TERMINATION

First subject in ----------------- Feburay 2016
Last patient out ----------------- June 2016
Study Report ----------------- July 2016

5. CONCLUSION

In total 25 patients were treated with insulin plant herbal tea (supplied by Nethra Organic Farm, Chennai) as supplement along with the respective regular on-going medications. All the patients were examined and prescribed the concern medications by the physician. Insulin plant herbal tea was dispensed to 25 patients for 90 days (3 months). Before starting the treatment, all the patients were examined for their blood glucose levels. After treatment every 15th day the examination was repeated. Out of 25 patients 23 were continued and two were discontinued because of their relocation within a month.

It was observed that the blood glucose level was lowered significantly with the consumption of insulin plant herbal tea. The product did not alter the blood pressure, Hb, and body weight significantly of any patients. It was also found that consumption of product in two patients converted type I diabetes to Type II diabetes over the 3 months. The examined product “Insulin Plant Herbal Tea” as a supplement showed satisfactory effect in 23 patients.
Dr. Supriya S. Jirge (Supriya R. Hyam)
Permanent Address: Omkar-Niwas, Sudha colony, Bordem, Bicholim, Goa-403504
Phone: 0832-2362657; mobile: 8408091337, Email: supriyahyam@gmail.com
Current Address: Indira Institute of Pharmacy, Sadavali, Devruk, Ratnagiri

PROFESSIONAL EXPERIENCE
Project Undertaken: 10 (As Principal investigator, Research professor, Research assistant and PhD Scholar)

Ongoing project: Development evaluation and extensive screening against skin cancer of targeted herbal delivery system

Sponsored by: Amsar Private Limited, India

PUBLICATIONS (19): International and national
Presentations: 10 International and national

COLLABORATIONS
1. Collaborative research work with Dr. S. S. Jalalpure, Deputy director of KLE University’s BSRC, Belgaum.
2. Collaborative research work with Dr. Pratima A. Tatke, Professor, C.U.Shah college of Pharmacy, SNDT women’s university, Mumbai

Approved by AICTE & PCI, New Delhi, Affiliated to University Of Mumbai & Recognised by D. T. E., Govt. of Maharashtra
The product supplied by Dr. Supriya S. Jirge which is intended to con sume by Diabetic patients as supplement was studied for period of February – June 2016 on 25 patients for three months each. Out of 25 patients 23 were continued and two were discontinued because of their relocation within a month.
It was observed that the blood glucose level was lowered significantly with the consumption of insulin plant herbal tea. The product did not alter the blood pressure, Hb, and body weight significantly of any patients. The examined product “Insulin Plant Herbal Tea” as a supplement showed satisfactory effect in 23 patients.

All twenty – five reports are enclosed herewith.

Dr. Swaphnil S. Dhane
B. A. M. S.
Reg. No. 62239 - A1
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<th>Date</th>
<th>Visit No.</th>
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<th>STUDY PROFILE</th>
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### Patient Profile

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### STUDY PROFILE

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Dr. Swapnil S. Dhane  
B.A. M.S.  
Reg. No.162239 - A1
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# Patient Profile

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## STUDY PROFILE

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[Signature]

Dr. Swapnil S. Dhane  
B.A.M.S.  
Reg. No. I62239 - A1
Patient Profile

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Dr. Swapnil S. Dhane  
B. A. M. S.  
Reg. No. 162239 - A1
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Name: Moreshwar S. Ogale  
Type of Diabetes: type II  
Ongoing medications: Glycomet 250 mg

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Dr. Swapnil S. Dhane  
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Patient Profile

Name: Vaibhav S. Surve
Type of Diabetes: type II
Ongoing medications: Glycomet 250 mg

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Dr. Swapnil S. Dhane  
B. A. M. S.  
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Note: Improvement in: Digestion, Mental condition
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Dr. Swapnil S. Dhane  
B. A. M. S.  
Reg. No. I62239 - A1
**Patient Profile**

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Dr. Swapnil S. Dhane  
B.A.M.S.  
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## Patient Profile

**Name**: Mrs. Gayatri M. Ogale  
**Type of Diabetes**: Type II  
**Ongoing medications**: Gliclazide 40mg

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Dr. Swapnil S. Dhane
B.A.M.S.
Reg. No. 162239 - A1
## Patient Profile

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## STUDY PROFILE

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Dr. Swapnil S. Dhane  
B.A. M. S.  
Reg. No. 162239 - A1
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Dr. Swapnil S. Dhane
B.A.M.S.
Reg. No. I62239 - A1
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Dr. Swapnil S. Dhane  
B.A.M.S.  
Reg.No.162239-A1
Patient Profile

Name: Mr. Sujit J. Bane  
Type of Diabetes: Type II  
Ongoing medications: Glycomet

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