INFORMED CONSENT DOCUMENT

Title of study: **"Open labelled, active controlled, randomized evaluation of the effect of Vidangadi Ghanavati in Prameha vis a vis Diabetes Mellitus (Type II)."**

1) Purpose of study:
Diabetes Mellitus (Prameha) is a global problem where in spite of good allopathic medications available, poor control on sugar levels is seen. Vidangadi Ghanavati (Vidangadi Yoga) is classical Ayurvedic medicine widely used in our hospital for its treatment. But it is not yet validated through a research project. Hence this study is designed to evaluate the effect of Vidangadi Ghanavati (Vidangadi Yoga) in Diabetes mellitus - type II (Prameha).

2) Expected duration of study: 3 months (90 days)

3) Drug Information:-
Patients will be distributed in two different groups on random basis. Vidangadi Ghanavati (Vidangadi Yoga) will be given to one group while patients from other group will receive metformin. Vidangadi Ghanavati (Vidangadi Yoga) is to be taken orally one tablet (500 mg) before food thrice daily with water. While metformin is to be taken orally one tablet (500 mg) after food twice daily with water. Both medicines will be provided to patients according to group. Metformin is well known medicine used in treatment of diabetes. Vidangadi Ghanavati (Vidangadi Yoga) is classical Ayurvedic medicine widely used in our hospital for treatment of Diabetes.

4) Procedure:
After patient reads this consent form and approve your participation in the study by signing it, patient's clinical examination and health history taking will be carried out. On next day patient will be asked to visit our hospital in morning on empty stomach for blood and urine tests. For urine investigation, patient will be given sterlised container and will be asked to collect urine sample from day's first morning urine, for investigation. Patient will be asked to bring the urine sample to our hospital during the visit. For blood investigation, 10 ml of blood will be withdrawn. The investigations will include – haemogram, blood cholesterol parameters, liver and kidney parameters, blood sugar fasting and glycosylated haemoglobin (HbA1c). Ninety minutes after lunch, 2 ml of blood will be withdrawn again for post lunch blood sugar level.
If patient is fulfilling the inclusion criteria he/ she will be included in the study. Patient will be allotted one group according to randomization table. Patient receive either Vidangadi Ghanavati (Vidangadi Yoga) or Tablet Metformin. Patient will be asked to visit our hospital for follow up after each 15 days till the end of three months. At each follow up

patient will be asked to come on empty stomach for fasting blood sugar checking. Two ml of blood will be drawn for fasting blood sugar checking. Ninety minutes after lunch, 2 ml of blood will be withdrawn again for post lunch blood sugar level. Patient will be aked about health complaints and detailed physical examination will be done. Each patient will receive medicines for next 15 days. At the end of 3 months all blood and urine investigation done while entering project will be done again.

5) Side effects:
No known side effects are noted due to use of Vidangadi Ghanavati (Vidangadi Yoga). Tablet metformin is known to show heartburn, stomach pain, nausea or vomiting, bloating, gas, diarrhea, constipation, weight loss, headache, unpleasant metallic taste in mouth in some patients.

6) Possible Benefits
Primarily the treatments are focused to improve the blood sugar level control.

7) Confidentiality of records:
Identity of every patient will be confidential and will not be revealed in any information released to third parties or published.

8) Responsibility of participants:
Patients voluntarily participating in the study need to co-operate and remain present for all follow ups. Patients missing consecutive follow ups will be withdrawal. It is his/her responsibility not to take any other medications for Diabetes in that period. Patient is also expected to communicate any sort of illness or any other medication taken for any purpose to the investigator. In case of emergency patient expected to contact on phone numbers given below at any time.

9) Withdrawal criteria:
Patient participation in the study is voluntary and patient can withdraw from the study at any time Refusal to participation will not involve any penalty or loss of benefits to which the subject is otherwise entitled.

10) Number of patients enrolled in study:
In this study minimum 60 patients will be enrolled.

11) Cost and Compensation:
There is no cost for patient for case paper, medicine or investigations for participating in study.

No compensation will be given to any patient for participating in study. In case of any unexpected health outcome occurred to the patient due to use of any of the medicines used in study patient will be entitled for compensation.

12) In case of emergency contact:

Dr.Krutika Jadhav-
Mobile no. 09967910927/08275377869
Post graduate resident,
PDEA's College of Ayurved and Research Centre &
Ayurved Rugnalaya and Sterling Multispecialty Hospital,
Sector 27, Near Bhel Chowk, Pradhikaran,
Pune 411044.

Dr. Shailesh Deshpande (MD Ayurved)
Mobile No. 09763104451
PDEA's College of Ayurved and Research Centre &
Ayurved Rugnalaya and Sterling Multispecialty Hospital,
Sector 27, Near Bhel Chowk, Pradhikaran,
Pune 411044.

Dr. Ila Bhor
Mobile No. 09423211003,
Secretary, Institutional Ethics Committee,
PDEA's College of Ayurved and Research Centre &
Ayurved Rugnalaya and Sterling Multispecialty Hospital,
Sector 27, Near Bhel Chowk, Pradhikaran,
Pune 411044.

DOCUMENTATION OF INFORMED CONSENT
TITLE OF THE PROJECT

"Open labelled, active controlled, randomized evaluation of the effect of Vidangadi Ghanavati in Prameha vis a vis Diabetes Mellitus (Type II)"

Case Paper No: - Date:-

Name: - Age:-

Date of birth: - Sex:-

1. I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal r rights being affected.
3. I understand that the sponsor of clinical trial, others working on the sponsors behalf, the ethics committee and the regulatory authorities will not need my permission to look at my health record's both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.
4. I agree not to restrict use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
5. I agree to take part in the above study.

Signature / Thumb impression of the subject / Legally Acceptable Representative:

Date: - ----------/----------/----------
Signatory's Name: ----------

Signature of the Investigator: ----------
Date: - ----------/----------/----------
Study Investigators Name: ----------

Signature of the Witness: - ----------
Date: - ----------/----------/----------
Name of the Witness: ----------