**CONSENT FORM**

**PART 1 of 2**

**INFORMATION FOR PARTICIPANTS OF THE STUDY**

Dear volunteers,

We welcome you and thank you for your keen interest in participation in this research project. Before you participate in this study, it is important for you to understand why this research is being carried out. This form will provide you all the relevant details of this research. It will explain you the purpose, risks and benefits, precautions and the information about how this study will be carried out. It is important that you read and understand the contents of the form carefully. This form may contain certain scientific terms and hence, if you have any doubts or if you want more information, you are free to ask the study personnel or contact the persons mentioned below, before you give your consent and also at any time during the entire course of the project.

1. Project Title : **Comparison of Metformin and Insulin**

**for the treatment of Gestational Diabetes Mellitus**

1. Name of the Investigator : Dr. DASARI PAPA,

Professor,

Department of Obstetrics & Gynaecology,

JIPMER.

Name of the Co-Investigator : Dr.Jaya Prakash Sahoo,

Assistant Professor,

Department of Endocrinology,

JIPMER.

Name of the Co-Investigator : Dr. Adhisivam,

Associate Professor,

Department of Neonatology,

JIPMER.

Name of the Co-Investigator : Dr. Nithya. R

Junior Resident

Department of Obstetrics & Gynaecology

JIPMER.

1. What is the purpose of this project / study?

* To assess the glycaemic control in antenatal mothers with GDM who receive metformin therapy.
* To compare the maternal and fetal outcomes between metformin group and insulin group in women with GDM.
* To determine the side effects of metformin on mother and fetus.
* To know the satisfaction of mothers towards metformin and insulin therapy.

1. What is the selection procedure of participants? ( Including the inclusion and exclusion criteria)

INCLUSION CRITERIA : Newly diagnosed pregnant women with

GDMA2 (willing to deliver in JIPMER).

EXCLUSION CRITERIA :

* Patients already on insulin
* Pre-gestational Diabetes.
* Insulin dependent diabetes
* PPROM
* Renal diseases

1. How will it be carried out (Procedure of the Study)?

Antenatal women attending obstetric OPD will be screened for GDM using 75 gm GTT and they will be diagnosed as GDM by IADPSG criteria11,

Fasting plasma glucose - ≥ 92 mg/dl

Ӏ hour plasma glucose - ≥ 180 mg/dl

ӀӀ hour plasma glucose - ≥ 153 mg/dl,

If 1 or more values are abnormal, then they are diagnosed as GDM.

The gestational age at which they will be screened will be based on the risk status. All the low and average risk women will be screened at 24 – 28 weeks of pregnancy. High risk women (marked obesity, previous history GDM, family history of diabetes) will be screened in the first trimester or in their first prenatal visit whichever is earlier12.

They will be randomized to either metformin or insulin group after giving advice regarding diet for 1 – 2 weeks. Informed consent will be taken as per the guidelines of clinical trial. They will be hospitalized and further investigation like blood sugar profile will be done once in 2 weeks, HbA1c will be done once in 12 weeks.

Metformin group will receive Tab. Metformin in combination with Vitamin B12 (Rejumet) 500 mg three times daily after meals. Dose adjustment will be done according to blood sugar profile and a maximum dose of 750 mg three times daily will be given. If the target blood sugar values are not achieved, Insulin will be added in small doses.

Insulin group will receive Inj. Human Mixtard 70:30 U according to body weight and gestational age. Dose titration will be done till the target glycaemic control13 is achieved.

Pre- prandial plasma glucose - ≤ 95 mg/ dl

Lower pre- prandial target - ≤ 90 mg/ dl

Ӏ hour after the start of meal - ≤ 140 mg/ dl

ӀӀ hour after the start of meal - ≤ 120 mg/ dl

If the blood sugars are controlled with the initial dose of metformin / Insulin patients will be discharged and will be followed up 2 weekly on OPD basis with a fasting and post prandial blood sugars done biweekly & HbA1c will be done once in 12 wks. Patients are admitted as and when necessary for Obstetric indications. Fetal monitoring will be initiated at or after 32 weeks and USG will be carried out as per the departmental/ unit protocol. Maternal and perinatal outcome will be noted as per the parameters mentioned below. Maternal satisfaction will be assessed using Predetermined Questionnaire5. Patients will be followed up till discharge after delivery.

1. What are the responsibilities of participants?

Patients are allowed to decide whether to enter the study or not. After opting in, patients are given full liberty to opt out at any stage. The responsibilities of participants are to take the medications regularly, follow the instructions, regular antenatal visit till delivery.

1. Expected duration of the subject participation?

From the time of diagnosis of Gestational Diabetes Mellitus till discharge after delivery.

1. What are the expected risks for the participants?

Less than minimal risks like lactic acidosis which is very rare.

1. What are the expected benefits of the research of the participants?

* Cheap
* Oral therapy
* Out patient management
* Does not cause hypoglycaemia
* Reduced rate of caesarean section

1. Whether my participation in this study be kept confidential?

Yes. Your participation in this study will be kept confidential. Names will not be revealed, when the study is being published. Records will be valid invariantly for the period of 3 years.

1. What happens in case of a study related injury?

If there are side effects like lactic acidosis, drug (metformin) will be stopped and consequences of lactic acidosis will also be treated. Alternative therapy with Insulin will be started.

1. Will participants be compensated for participation in this trial?

No. You will not be given any compensation for participation in this trial.

1. Will participants be compensated for foreseeable & unforeseeable risks related to research study leading to disability or death?

Yes, you will be compensated for risks related to research study according to Govt. of India Gazette notification vide GSR 53(E).

1. Can I withdraw from study at any time during the study period?

Yes, you can with draw at any time during the study period. This decision will not affect your regular medical care.

1. Possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, this should be mentioned

Data obtained from the research may be used for secondary research purposes and it will be mentioned & shared with others, if there are any new findings.

For any study related queries, you are free to contact,

Name of the contact person : Dr. PAPA DASARI

Official address : Professor

Department of Obstetrics & Gynaecology

JIPMER, Puducherry- 605006.

Contact Number : 9442566883

Place : Puducherry Signature of the Investigator

Date : Signature of the Witness

**CONSENT FORM**

**PART 2 OF 2 - PARTICIPANT CONSENT FORM**

Participant’s Name :

Address :

Title of the project : **Comparison of Metformin and Insulin**

**for the treatment of Gestational Diabetes Mellitus**

The details of the study has been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and the opportunities to ask questions. 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 rights being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purposes. I also received a copy of the ‘consent form 1of 2’ giving the “Information for participants of the study”. I give my full consent to participate in the above study.

Signature of the Participant : Date :

Signature of the Witness : Date :

Signature of the Investigator : Date :