Patient Addressograph

Consent to Progesterone Treatment in Early Pregnancy

◯ I have had a chance to read the Tommy's Leaflet regarding progesterone treatment in early pregnancy.

◯ I am aware of the NICE Guideline which recommends progesterone treatment for women with early pregnancy bleeding and at least one previous miscarriage.

◯ I am aware that research (Prism trial) has shown that some women with early pregnancy bleeding and 3 or more previous miscarriages are less likely to miscarry if they have progesterone.

◯ I am aware that research has shown the benefit is less clear for those with fewer than three miscarriages who have early pregnancy bleeding.

◯ I am aware that there is no benefit for women who have not have a previous miscarriage.

◯ Research has shown that there is no benefit for women who are not bleeding in early pregnancy even if they have had three or more previous miscarriages.

◯ Progesterone will only be started after I have a scan that shows I have a pregnancy in my womb.

◯ The treatment consists of micronised progesterone vaginal pessaries which are inserted twice a day, unless the pregnancy stops growing or I miscarry, as recommended by NICE.

◯ I am aware that the preparation used in the PRISM trial was a micronised (natural) progesterone called Utrogestan®. It is not currently licensed for use in pregnancy. It is not suitable for vegans due to animal-based ingredients.

◯ I am aware that the dose recommended by NICE is 400 mg twice a day, as vaginal pessaries, from the time an intrauterine pregnancy is confirmed by ultrasound scan to 16 weeks of gestation.

◯ I am aware this unit can use other micronised vaginal progesterone preparations, such as Cyclogest 400 mg twice a day, as vaginal pessaries, from the time an intrauterine pregnancy is confirmed by ultrasound scan to 16 weeks of gestation. This preparation is suitable for vegans.

◯ I am aware the use of progesterone was considered safe by the PRISM trial as there was no increase in harmful effects for mothers or babies in the womb nor any increase in congenital abnormalities recorded in the babies born to mothers in the trial.

◯ I am aware there is no long term information on the effects to the children born to mothers who used extra progesterone in pregnancy, particularly between 12 and 16 weeks of pregnancy.

◯ That the maximum benefit of progesterone treatment is achieved by 12 weeks of gestation.

◯ I am aware there are animal studies showing harmful effects on male babies' testes, and other hormone-producing glands (pituitary and adrenal) as well as an effect on brain development with progesterone use between 6-16 weeks. As these effects were seen in animals it is unknown whether this would be seen in human boys.

◯ I have none of the following: a history of liver tumours; severe kidney disease; current genital or breast cancer; severe arterial disease (angina or high blood pressure, previous heart attack or stroke); previous or increased risk of blood clots; jaundice related to pregnancy; severe itch related to pregnancy; pemphigoid gestationis; acute porphyria; diabetes; epilepsy; moderate to severe asthma; severe migraines; depression requiring medication; previous reaction to progesterone.

◯ I understand some of the side effects include: headache; dizziness; mood change; breast pain; constipation; vaginal soreness; oily discharge from the pessary.

◯ I am aware this is an unlicensed medication though is recommended by Royal College of Obstetricians and Gynaecologists and the National Institute of Clinical Excellence.

◯ I have had my questions about this treatment answered.

◯ **Having been fully informed of the options, I DO/DO NOT consent to progesterone treatment (circle)**

◯ Gestation by Ultrasound Scan, TV or TA (circle) ……

◯ Number of previous pregnancy losses ……..

◯ Bleeding in this pregnancy ……..

◯ Name of Micronised progesterone given ……

◯ Dose ……

◯ Duration (ie to 12 weeks or 16weeks) ……

Patient Name: ……Patient Signature: ……..

Date: ……

Staff Name: …… Staff Signature: …….

Date: ……..