			3 calendar days The Sponsor will submit reports to the HPRA using the online reporting form found at the following link: http://www.hpra.ie/homepage/medicines/regulatory-information/clinical-trials/reporting-serious-adverse-events. As an alternative reports can also be faxed to the HPRA at 01 676 2517.	
39	12.5 Data Safety Monitoring Board (DSMB)	The DSMB will convene 4 monthly	The DSMB will convene 6 monthly	The frequency of DSMB meetings was discussed and reviewed at the first DSMB meeting and was changed in light of the reduced rate of recruitment and generated data.
56	Appendix Patient information leaflet	Version 2 dated 29/01/15	Version dated 26.01.16	Insertion of text to inform subjects of third party access to medical records

10 STUDY POPULATION

10.1 DISPOSITION OF PATIENTS

Figure 2 shows the number of subjects contributing to the population for this study. The total number of women screened in both hospitals was 47 women. Of these 31 were eligible to entry criteria. 7 out of those 31 women didn't consent to participate in the study.24 patients gave initial consent for the study, two withdrew at different stages of the study, one had late fetal demise and 21 continued to delivery

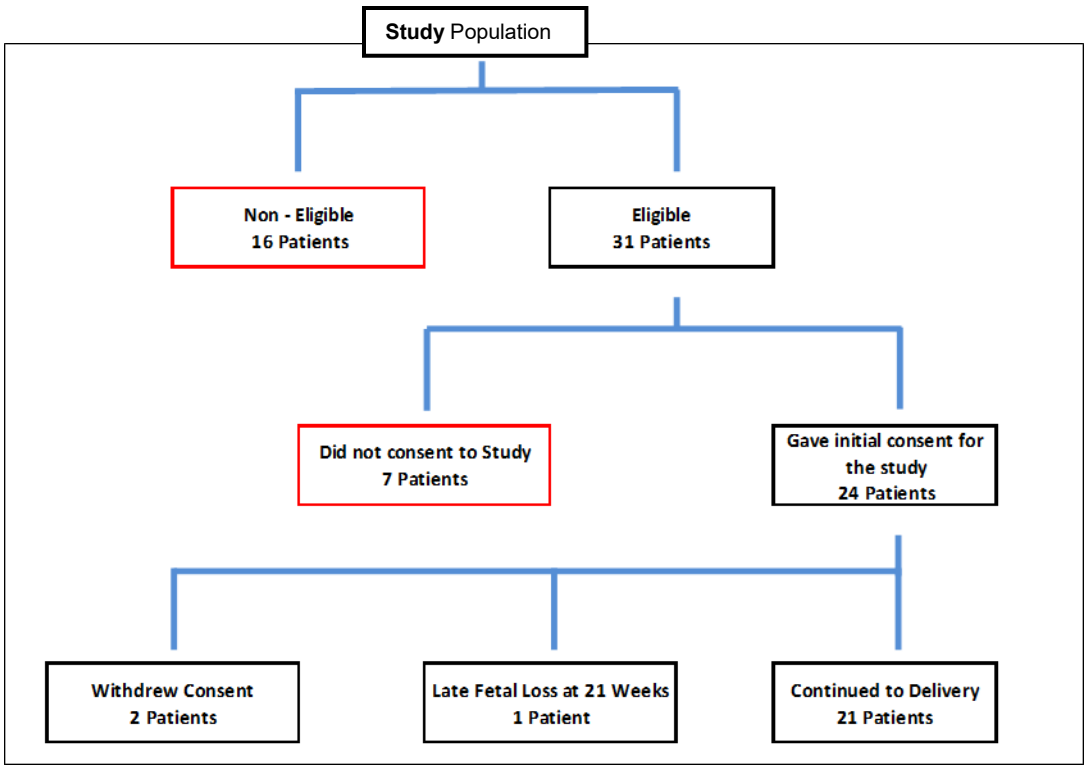

Figure 2: Study Population

Figure 3 shows the number of women who were deemed ineligible for entry of the study and shows different subgroups. 16 (34%) patients were ineligible to enter the study. 8 out of 16 had a miscarriage before 12 weeks gestation (17% of total number of patients screened and 50% of total number of women screened and were ineligible for to study entry). 2 had difficulty communicating in English language and 2 were on Aspirin in the first trimester before the recruitment phase, 2 had twin pregnancies, one case attended the clinic after 12 weeks gestation and lastly one patient had recently been diagnosed with type 2 diabetes mellitus, less than 6 months prior to recruitment

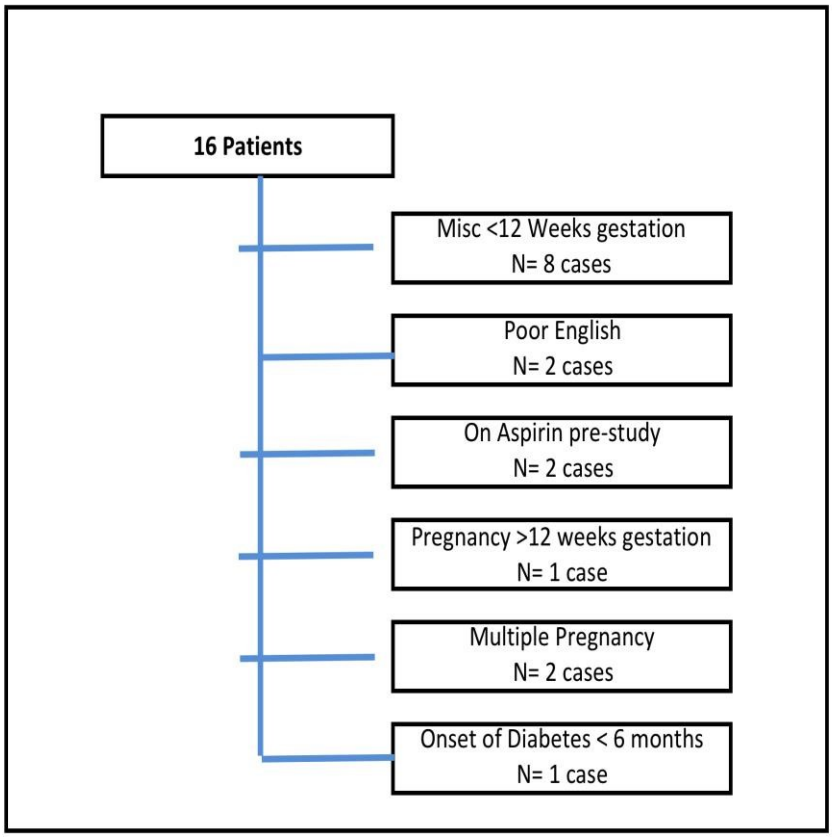

Figure 3: The number of patients' ineligible for study entry

10.2 PROTOCOL DEVIATIONS

Table 5 gives details of protocol deviations observed during the study.

Table 5 Protocol deviations

Deviation	*Site: Rotunda*	*Site: Coombe*
Consent Procedures	2	0
Inclusion/Exclusion Criteria	0	0
Patient Compliance with IMP	4	0
Laboratory Assessments	3	1
Study Procedures	5	0
Serious Adverse Event Reporting	3	0