# Clinical Trials Data KIT - Document 36

# Exploring the Role of At-home Semi-Quantitative Pregnancy Tests for Medical Abortion Follow-up

## Clinical Trial: https://clinicaltrials.gov/study/NCT01150279

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Women age greater than or equal to 18 years\n\* Gestational age less than or equal to 63 days by last menstrual period (LMP), ultrasound or clinical assessment\n\* Agrees to return for follow-up visit and willing to provide an address and/or telephone number for purposes of follow-up\n\* Able to consent to study participation.\n\nInclusion Criteria for Mexico:\n\n\* Gestational age \\<\_ 70 days from LMP\n\* Eligible for mifepristone- misoprostol medical abortion according to clinic guidelines\n\* Willing to follow instructions of the provider regarding use of the at-home pregnancy test\n\* Agrees to provide test results by phone to study coordinator on morning of schedule follow-up visit\n\* Willing to provide an address and/or telephone number for purposes of follow-up\n\* Agrees to return for standard follow-up visit\n\* Wishes to participate in the study\n\* Having easy access to a telephone and transportation\n\* Able to consent to study participation\n\nExclusion Criteria:\n\n\* Women less than 18 years of age\n\* Women not eligible for medical abortion services\n\* Women unable to provide contact information\n\* Women unable to sign the consent form\n\nExclusion Criteria for Mexico:\n\n\* Women not eligible for medical abortion services\n\* Women unable to provide contact information\n\* Women unable to sign the consent form",  
 "healthyVolunteers": true,  
 "sex": "FEMALE",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT"  
],  
 "studyPopulation": "Women presenting to clinic seeking medical abortion",

Question:  
Based on the following clinical trial information, would a patient with a KIT gene mutation be eligible for the clinical trial?

Answer:  
This clinical trial is for evaluating medical abortion. The criteria focus on pregnancy and ability to consent, not genetic markers. A KIT gene mutation is not mentioned in the inclusion or exclusion criteria. Therefore, having a KIT gene mutation \*in itself\* would neither include nor exclude a patient. A patient with a KIT mutation would need to meet \*all other\* inclusion criteria (being a woman, age 18 or older, within the specified gestational age, willing and able to provide contact information and consent, etc.) and not meet any of the exclusion criteria (being ineligible for a medical abortion) to be eligible for the trial.