# A Randomised Controlled Feasibility Trial of the Mechanisms of the Fertility Enhancing Effect of Lipiodol in Women

ACTRN12621001164886

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| **Status** | RECRUITING |
| **Phase** | Phase 3 |
| **Sponsor** | Professor Neil Johnson |
| **Enrollment** | 45 participants |

## Plain Language Summary

Lipiodol is an oil-based contrast dye used in a fertility procedure called a hysterosalpingogram (HSG) — a test that checks whether the fallopian tubes are open. For decades, doctors have noticed that some women become pregnant more easily after having this oil-based dye test — a surprising 'fertility bonus' effect. Despite this being well-documented, nobody fully understands why it happens.

This feasibility study will look for biological clues by examining tissue samples from the uterus (endometrium), fallopian tubes, and peritoneal lining in women who have had a lipiodol HSG, a water-soluble contrast HSG, or no HSG at all, prior to undergoing a hysterectomy. The goal is to identify which tissue-level changes are most strongly linked to the lipiodol effect.

You may be eligible if you are a woman under 50 years old with a regular menstrual cycle suggesting ovulation and are scheduled for a hysterectomy for a benign (non-cancerous) gynaecological reason. Women with large fibroids (over 10cm), known malignancy, sexually transmitted infections, or those scheduled for a purely vaginal hysterectomy are not eligible.

## Key Eligibility Criteria

### Inclusion (1)

- Women of reproductive age (<50 years) and who have a regular cycle that suggests ovulation, who are due to undergo hysterectomy for benign gynaecologcical conditions

### Exclusion (5)

- Any fibroid larger than 10cm in maximum dimension; (this change was made after 2 participants were recruited and at the initial screening stages of the MoFEEL trial)
- Known Malignancy;
- Known carrier of organism(s) associated with sexually transmitted infection (STI);
- Women scheduled for purely vaginal hysterectomy.
- Women will complete our modification of the standardised World Endometriosis Research Foundation Endometriosis Phenome Harmonisation Project (EPHect) patient questionnaire, which is appropriate for any woman with benign gynaecological disease entering a research trial.

## Locations (1 total)

Flinders Medical Centre - Bedford Park, SA, Australia