

A patient satisfaction evaluation study of Bemfola (recombinant FSH) administered with a 12mm needle or a 4mm needle in the treatment of subjects undergoing invitro fertilisation (IVF)

ACTRN12618000728235

Status	RECRUITING
Sponsor	Dr Rachael Knight
Enrollment	112 participants

Plain Language Summary

IVF (in vitro fertilisation) involves daily hormone injections to stimulate egg production. One medication commonly used is Bemfola, a form of FSH (follicle-stimulating hormone) that is currently given using a 12mm needle. In other areas of medicine — like insulin for diabetes — a move to shorter 4mm needles has been shown to be just as effective while being more comfortable for patients. This study is investigating whether the same switch could benefit women undergoing IVF.

Participants will be randomly assigned to use either the standard 12mm needle or a shorter 4mm needle throughout one IVF treatment cycle (approximately 28 days). At each clinic visit, they'll complete a short satisfaction questionnaire, and safety will be closely monitored. The goal is to see if the smaller needle is equally safe and potentially more comfortable.

You may be eligible if you are a female aged 18 to 38 with a diagnosis of infertility and are about to begin an IVF cycle using Bemfola. Women with tumours of the pituitary gland, unexplained ovarian cysts, unexplained vaginal bleeding, ovarian or uterine cancer, or failed ovaries are not eligible. If you're starting IVF and interested in contributing to research that could make injections more comfortable for future patients, ask your fertility clinic about this study.

Key Eligibility Criteria

Inclusion (3)

- Female subjects aged 18-38 years
- Written informed consent prior to any of the study procedures including discontinuation of prohibited medications
- A diagnosis of infertility

Exclusion (8)

- Tumours of the hypothalamus or pituitary gland
- Enlarged ovaries
- Unexplained ovarian cyst
- Unexplained vaginal or uterine bleeding
- Cancer of the ovaries, uterus or breasts
- ... and 3 more (see full listing online)

Locations (1 total)

VIC, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12618000728235>

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