

**Effect of in vitro fertilisation (IVF) hormonal
therapy on metabolic, endocrine and
inflammatory status in IVF-conceived
pregnancy**

NCT03426228

Chapter 1: Aim of the study and Objectives

1. To explore the short-term effects of IVF hormonal therapy on maternal metabolic and inflammatory status, including:
 - i. Risk of glucose intolerance and insulin resistance
 - ii. Risk of other metabolic, endocrine and inflammatory disturbances (including lipid profile, gut microflora and thyroid function)
2. To identify possible early predictors of GDM and other metabolic-related adverse outcomes in IVF-conceived pregnancies.

Chapter 2: General Methods

2.1. Ethics and Consents

Approval to conduct the study was first granted by the University of Warwick's Biomedical and Scientific Research Ethics Sub-Committee (BSREC). The study protocol was also reviewed by the two main health authorities in the UAE.

2.2. Study Design

The presented study is a longitudinal quantitative cohort study (non-experimental), whereby blood samples were collected at different stages during IVF therapy.

2.3. Study Setting

The study took place at in three fertility clinics in the UAE. At the clinics, pre- and post-fertility treatments and in-house obstetric facilities are provided, including blood tests, scans, IVF procedures and in-house genetic testing. Most patients are followed up to the point of delivery.

2.4. Study Population

- **Pregnant group:** received IVF therapy and tested positive for pregnancy at 4 weeks, and continued taking IVF hormonal therapy until 12 weeks of pregnancy.
- **Non-pregnant:** received IVF therapy and tested negative for pregnancy at 4 weeks, and stopped taking IVF hormonal therapy at that point.

2.5. Sampling Technique

The non-probability convenience sampling method was used to recruit participants for the study. Patients who were to start a fresh IVF treatment at any of the IVF Clinic branches and meeting the inclusion criteria were eligible to participate.

2.6. Study Protocol

After an overnight fast of 8 hours, there was collection of 10 ml of blood at four pre-defined time points during the IVF protocol:

1. **Phase 1** – At baseline, egg maturation (starting IVF therapy)
2. **Phase 2** – Week 2 – Egg retrieval (OPU procedure)
3. **Phase 3** – Week 4 – At pregnancy test (β -HCG test)
4. **Phase 4** – Week 12 (one week after completing IVF hormonal therapy for pregnant group).

2.7. Blood Tests

A trained nurse was in charge of measuring anthropometrics and clinical parameters (e.g. weight and blood pressure), in addition to taking fasting blood samples. The socio-demographics, medical and pregnancy histories of each patient

were recorded in their file. Blood tests were conducted at in the phlebotomy room and transferred to the lab (in-house) for analysis. Tests results were available on the clinics internal server at the end of each day.

Table 1: List of Blood Tests at Each Stage of the Study

Type of Tests	Phase 1- Baseline (Start IVF treatment)	Phase 2- Week 2 (Egg retrieval)	Phase 3- Week 4 (β - HCG test)	Phase 4- Week 12 (Final)
Female reproductive hormones: FSH, LH, oestrogen, progesterone	✓	✓	✓	
HbA1c	✓			✓
Fasting glucose	✓	✓	✓	✓
Fasting insulin	✓	✓	✓	✓
TSH	✓			✓
Fasting lipid profile	✓			✓
Adiponectin	✓			✓
LBP	✓			✓
β -HCG pregnancy	✓		✓	
Body weight	✓			✓

*Green highlight represents stage where non-pregnant vs. pregnant women groups were distinguished; FSH: follicle-stimulating hormones; LH: luteinizing hormone; HbA1c: glycated haemoglobin A1c; TSH: thyroid-stimulating hormone; LBP: lipopolysaccharide binding protein; β -HCG: beta-human chorionic gonadotrophin

Appendix 1. Anthropometrics and Medical History Questionnaire

Effects of fertility drugs on glucose homeostasis, and other metabolic parameters on patients undergoing In Vitro Fertilisation (IVF) [NCT03426228](#)

Subject Name:

Telephone No:

E-mail:

Age	
Height	
Weight	
BMI	
Nationality	
Smoking	
Parity	

Past Illness and Surgeries

Drug History

Family History

Women Health

Cycle:	Regular	Irregular
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History of GDM:
Previous IVF trials:

Blood Analysis

Type	Level/ Unit	Frequency
Fasting glucose		4 times
Serum insulin		4 times
Lipid profile		Twice
FSH, LH		4 times
Oestrogen, Progesterone		4 times
Beta-HCG		Once

Appendix 2. Participants Study Tests

Effects of fertility drugs on glucose homeostasis, and other metabolic parameters on patients undergoing In Vitro Fertilisation (IVF) [NCT03426228](#)

IVF MEDICATION & METABOLIC PARAMETERS				
Baseline	Week2	Week 2	Week 4	Week 12
Start IVF Therapy	Pre-OPU	Embryo Transfer	+/- β -HCG	Final
A1C Fasting glucose Serum insulin Lipid profile Hormonal Profile (AMH, LH, FSH, progesterone, oestrogen) TSH LBP Adiponectin	Fasting glucose Serum insulin Hormonal profile (LH, progesterone, oestrogen)	Hormonal Profile (progesterone, oestrogen)	Fasting glucose Serum insulin Hormonal profile (progesterone, oestrogen, β -HCG)	HbA1c Fasting glucose Serum insulin Lipid profile TSH LBP Adiponectin

