Can antioxidants supplementation improve ICSI/IVF outcomes in women undergoing IVF/ICSI treatment cycles? Randomised controlled study.

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Good oocyte quality and maturity are important prerequisites for higher fertilization and implantation rates in IVF/ICSI treatment cycles. Reactive oxygen species (ROS) are produced within ovarian follicles, especially during ovulation process, and...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23255

Bron
NTR

Verkorte titel
ANTIOX

Aandoening

ANTIOXIDANTS; INFERTILITY; OOCYTE QUALITY; IVF;ICSI

Ondersteuning

Primaire sponsor: Egyptian International Fertility IVF center- Private center, Cairo , Egypt
Overige ondersteuning: fund= initator= sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Number of retrieved oocytes;
2. Number of mature oocytes;
3. Number of embryos obtained.

Toelichting onderzoek

Achtergrond van het onderzoek

BACKGROUND:

Good oocyte quality and maturity are important prerequisites for higher fertilization and implantation rates in IVF/ICSI treatment cycles. Reactive oxygen species (ROS) are produced within ovarian follicles, especially during ovulation process, and it is thought that increased ROS activity may be a cause of impaired oocyte maturation and higher rate of failure of IVF/ICSI cycles. It has been approved that antioxidants administration improves sperm numbers and morphology. In contrast, the effect of antioxidants did not studied properlly yet in women undergoing IVF/ICSI treatment.

METHODS:

Randomized controlled trial using computer generated list and closed opaque envelops comparing the effect of antioxidants supplementation on IVF outcomes will be conducted on 170 women with different indications for IVF/ICSI, will be randomized into 2 groups. Study group (n=85) will be supplemented with antioxidant supplementation daily from the cycle preceding IVF/ICSI cycle and the control group (n=85) will not.

Primary outcome: Number of retrieved oocytes, number of mature oocytes, and number of embryos obtained.
Secondary outcomes: Implantation rate, clinical pregnancy rate, duration of stimulation, amount of FSH and adverse events.

Doel van het onderzoek

Good oocyte quality and maturity are important prerequisites for higher fertilization and implantation rates in IVF/ICSI treatment cycles. Reactive oxygen species (ROS) are produced within ovarian follicles, especially during ovulation process, and it is thought that increased ROS activity may be a cause of impaired oocyte maturation and higher rate of failure of IVF/ICSI cycles. It has been approved that antioxidants administration improves sperm

numbers and morphology. In contrast, the effect of antioxidants did not studied properlly yet in women undergoing IVF/ICSI treatment.

Onderzoeksopzet

1. Oocyte quality on day of ovum pickup;

2. Fertilization rate on day 2-5;

3. Biochemicalpregnancy rate after 14 days from embryo transfer;

4. Clinical pregnancy rate: 7 weeks pregnancy plus fetal heart rate by ultrasound.

Onderzoeksproduct en/of interventie

At the start of down regulation treatment or previous cycle precceding the IVF cycle, patients will be randomized into two groups. The antioxidant group (study group) will receive oral antioxidants medication (Octatron) 2 tablets/day up to the pregnancy test.

1. Ovarian stimulation will be initiated with HP- FSH (HP FSH; Fostimon; IBSA, Egypt) from cycle day 2 or 3 and continued until the day of ovulation induction. A fixed dose of HP-FSH will be used, either 225 IU - 300 IU per day for the first 5 days, according to age, body mass index, basal FSH level, and antral follicle count. After 5 days, doses will be adjusted according to ovarian response;

2. Different downrgulation protocols will be used either daily midluteal long GnRH protocol, 01 mg, SC, Decapeptyl(Ferring,) or flexible GnRH antagonist ganirelix (Cetrotide 0.25 mg; Organon) is initiated and continued up to and including the day of ovulation induction;

3. When at least two follicles reach a size of 18 mm, both groups will receive hCG (10,000 IU SC) for final oocyte maturation, followed by OPU 34-36 hours later.

Contactpersonen

Publiek

Post Office Box 109
Mohamed A.F. Youssef
Dept. Obstetrics and Gynaecology, Kasr-Alainy Hospitals, Faculty of Medicine-Cairo University, Elmalek Al Saleh
Cairo 11559

Egypt
+20 2148088826

Wetenschappelijk

Post Office Box 109
Mohamed A.F. Youssef
Dept. Obstetrics and Gynaecology, Kasr-Alainy Hospitals, Faculty of Medicine-Cairo University, Elmalek Al Saleh
Cairo 11559
Egypt
+20 2148088826

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Female age 18 – 45 years;

2. Menstrual cycles between 25 and 34 days;

3. Absence of uterine abnormalities;

4. Absence of uterine abnormalities;

5. Has an indication for IVF/ICSI.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Poor sperm quality with counts less than 1 million or azospermia.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2011
Aantal proefpersonen:	170
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-03-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2687
NTR-old	NTR2816
Ander register	EIFCIVF : 2000
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A