Luteal Phase Support in MOH/IUI treatment (LUMO study)

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24508

Bron
NTR

Verkorte titel
LUMO

Aandoening

Unexplained Infertility/ sub fertility

Ondersteuning

Primaire sponsor: ZonMW
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pregnancy within 6 months of treatment, leading to Live birth.

Toelichting onderzoek

Achtergrond van het onderzoek

The LUMO study is a multicenter, randomized controlled trial that evaluates the effectivity of luteal phase support in MOH/IUI treatment.

Participating sites consist of academic and non-academic hospitals and fertility clinics in The Netherlands. There are two treatment arms (MOH/IUI treatment with LPS vs regular MOH/IUI treatment) with a non-blinded superiority design. Participants are randomly distributed across both treatment arms for the entire study-period (six months, non-crossover).

Eligibility criteria are: 1) couples starting IUI with Mild Ovarian HyperStimulation (MOH), with the intend to receive this treatment for at least six months. 2) Indication for MOH/IUI treatment is in accordance with current (dutch) NVOG guidelines; Diagnosis of unexplained (primary or secondary) infertility with Hunault <30% (or >30%, after an expectant management period of at least 6 additional months). Total mobile sperm count (VCM) >10 million. 3) Females aged >18 years with regular menstrual cycle.

(Mild) Ovarian stimulating treatment and insemination are according to regular treatment protocol. Females assigned to the treatment group start LPS, applying 3dd200mg Utrogestan in vaginal capsules, on the day of IUI. Treatment is continued until the onset of menstruation, a negative pregnancy test, miscarriage or confirmed vital intra-uterine pregnancy at 7 weeks gestation.

Main outcome is pregnancy within 6 months of treatment, leading to Live birth. Secondary outcomes are; Clinical pregnancy rate. Miscarriage rate. Multiple pregnancy rate. Pregnancy complications. Perinatal outcomes. Side effects and compliance to therapy. Added Medication Costs. Budget impact.

The analyses will include a cost-effectiveness analysis.

Doel van het onderzoek

We hypothesize that the addition of luteal phase support (by the use of exogenous vaginal Progesterone) during MOH/IUI cycles will lead to increased live birth rates. Natural feedback mechanisms and hormone release are affected by artificially stimulated cycles and induced ovulation. LPS positively affects the Progesterone level and length of the luteal phase, both critical for implantation and maintenance of early pregnancy. LPS following oocyte pickup in IVF/ICSI treatment is associated with increased pregnancy and live birth rates and hence routine in the Netherlands. According to a recent meta-analysis by Green et al., LPS could be effective in MOH/IUI treatment as well, with live birth occurring more frequently in patients receiving exogenous Progesterone (RR 1.76, 95% CI 1.29-2.40). The studies in the meta-analysis are often single-center based, fail to obtain individual power, included only a single treatment cycle and/or evaluate various types of luteal support. Besides, eligibility criteria did not always correspond with the baseline characteristics of the 15.000 couples that annually

proceed to MOH/IUI treatment in the Netherlands. Therefore, a large multicenter RCT (randomized controlled trial) will be of great value to confirm the findings in the meta-analysis and provide the basis for application of this strategy in daily practice.

The application of LPS in MOH/IUI treatment is expected to be cost-effective. With increased success rate of MOH/IUI treatment, the total amount of IUI treatment cycles is reduced and less couples will need to proceed to (expensive) IVF treatments to fulfill their child wish. The impact of LPS on total expenses will be minimal, as Utrogestan (vaginal capsule containing Progesterone) will cost approximately one euro a day per couple for the proposed dosage and use. Based on the former studies in the meta-analysis, there is no reason to assume a substantial increase in multiple pregnancy rate. LPS is already widely used in fertility treatment, potential risks are limited, and implementation can be done relatively effortlessly.

Onderzoeksopzet

Start of first MOH/IUI cycle, end of first MOH/IUI cycle, start/end of any following treatment cycle. In case of pregnancy: <3 months after delivery.

Onderzoeksproduct en/of interventie

Exogenous progesterone (Utrogestan)

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Couples starting IUI with Mild Ovarian HyperStimulation (MOH), with the intend to receive this treatment for at least six months.
- Diagnosis of unexplained (primary or secondary) infertility
- Hunault <30% (or >30%, after an expectant management period of at least 6 additional months).
- Females aged >18 years with regular menstrual cycle.
- Total mobile sperm count (VCM) >10 million.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Uterine anomalies
- Endometriosis gr 3-4
- Endocrine anomalies

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2022
Aantal proefpersonen:	1008
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

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	NL9766
Ander register	METC UMC : volgt

Resultaten