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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24508

Source
NTR

Brief title
LUMO

Health condition

Unexplained Infertility/ sub fertility

Sponsors and support

Primary sponsor: ZonMW
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Clinical pregnancy rate (Number and rate op patients that achieve a clinical pregnancy within

6 months). Miscarriage rate (Number and rate of patients that experience a miscarriage (<16weeks gestation) within 6months). Multiple pregnancy rate (number of pregnancies with 2 or more fetuses, <6 months). Pregnancy complications (pregnancies complicated by preterm labor (<37weeks), loss of pregnancy (>16 weeks gestation), gestational diabetes, preeclampsia, HELLP syndrome or pregnancy induced hypertension, within one year). Perinatal outcomes (stillbirth, live birth, perinatal death <6 weeks, gestational age and birthweight). Side effects (e.g. nausea, stomach ache, vaginal discharge, other (self reported) side effects) within treatment cycle) and compliance to therapy (use of medication as prescribed during treatment cycles). Added Medication Costs (increase in total therapy costs due to the addition of utrogestan). Budget impact (economic assessment that estimates financial consequences of adopting a new intervention).

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

Exogenous progesterone (Utrogestan)

Contacts

Public
UMC Utrecht
Katja Drechsel

+31624343118
Scientific

UMC Utrecht
Katja Drechsel

+31624343118

Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-12-2022
Enrollment:	1008
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9766
Other	METC UMC : volgt

Study results