Studier av graviditetsutfall hos kvinnor som genomgår frys-ET i naturlig cykel

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Lutal support with vaginal progesteron after transfer of frozen, thawn embryos in natural cycles will improve the live birth rate, compared to natural cycles without lutal phase support

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

Samenvatting

ID

NL-OMON28205

Bron
NTR

Verkorte titel
Lutstud

Aandoening

luteal support, progesterone, frozen embryo transfer, natural cycle

Ondersteuning

Primaire sponsor: Uppsala Universty
Overige ondersteuning: Ferring läkemedel AB

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Live born child

Toelichting onderzoek

Achtergrond van het onderzoek

Randomized controlled trial comparing pregnancy outcome after frozen embryo transfer in natural cycles with or without lutael phase support with vaginal progesterone

Doel van het onderzoek

Lutal support with vaginal progesteron after transfer of frozen, thawn embryos in natural cycles will improve the live birth rate, compared to natural cycles without lutal phase support

Onderzoeksopzet

The primary endpoint live birth rate will be calculated after all data from the deliveries has been reported. The secondary outcome measure ongoing pregnancy will be used for interim analysis and finally when the study is closed to new patients and data are available. Serum anaylysis will be performed after closing the study.

Onderzoeksproduct en/of interventie

The treatment (intervention) is substitution with vaginal tablets of Lutnius (progesterone) 100 mg two times daily, started on the day of embryo transfer and continued until 8 weeks of pregnancy, compared to no substitution. Patients are randomized after the embryo transfer, using closed envelopes. Blood samples are taken on the day of embryo transfer for analysis of serum progesterne and cytokine levels. Primary outcome is the rate of live birth per embryo transfer. Secondary endpoints are pregnancy rate, ongoing pregnancy rate, misscarriage rate and serum levels of progesterone and cytokines.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients planning frozen embryo transfer in a natural cycle

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patient who do not want to participate.
Adverse effect of Lutinus.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestopt

(Verwachte) startdatum:	01-02-2013
Aantal proefpersonen:	500
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	05-12-2013
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	NL4152
NTR-old	NTR4305
Ander register	: Lutinusstudien
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Datum resultaten gemeld:	01-06-2024
Totaal aantal deelnemers:	488

Samenvatting resultaten
Supplementation with vaginal tablets of progesterone after frozen-thawed embryo transfer in natural cycles significantly improves the number of live births.

Deelnemers doorstroom
In the present study, 672 infertile women were invited to participate in this RCT. Of these, 500 study entries (74.2%) were included in the study and after additional exclusions 488 women were finally included.

Onderzoeksvariabelen / uitkomstmaten
The primary outcome was LBR. Secondary outcome measures were pregnancy, biochemical pregnancy, clinical pregnancy and miscarriage rate, and if there was a possible association between the serum progesterone concentration on day of embryo transfer and LBR.

Datum eerste publicatie onderzoek
16-08-2022

URL result
Type
ext
Naam
Human reproduction
URL