Progesterone supplementation in natural cycles improves live birth rates after embryo transfer of frozen-thawed embryos—a randomized controlled trial

Published: 05-12-2013
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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

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28205

Source
NTR

Brief title
Lutstud

Health condition

luteal support, progesterone, frozen embryo transfer, natural cycle

Sponsors and support

Primary sponsor: Uppsala Universty
Source(s) of monetary or material Support: Ferring läkemedel AB

Intervention

Outcome measures

Primary outcome

Live born child

Secondary outcome

Prennancy rate, ongoing pregnancy rate, misscarriage rate. Serum levels of progesterone and cytokines

Study description

Background summary

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

Study objective

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

Study design

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.

Intervention

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.

Contacts

Public
Associate Professor
Dept of Womens and Childrens Health,
Uppsala Universty.

Kjell Wånggren
[default]
The Netherlands
Scientific
Associate Professor
Dept of Womens and Childrens Health,
Uppsala Universty.

Kjell Wånggren
[default]
The Netherlands

Eligibility criteria

Inclusion criteria

Patients planning frozen embryo transfer in a natural cycle

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2013
Enrollment:	500
Type:	Actual

Ethics review

Positive opinion

Date:	05-12-2013
Application type:	First submission

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	NL4152
NTR-old	NTR4305
Other	: Lutinusstudien
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Results posted:	01-06-2024
Actual enrolment:	488

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

Participant flow
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.

Outcome measures
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.

First publication
16-08-2022

URL result
Type
ext
Naam
Human reproduction
URL