Eeva* Pregnancy Investigational Clinical Study (EPIC): A Post-Market Follow-Up Study.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39968

Source
ToetsingOnline

Brief title
EPIC study

Condition

- Other condition

Synonym
subfertility, unable to get pregnant

Health condition

subfertiliteit

Research involving
(Surplus) Embryos

Sponsors and support

Primary sponsor: Auxogyn Inc.
Source(s) of monetary or material Support: Auxogyn Inc.,bedrijf Auxogyn Inc.

Intervention

Keyword: Eeva, embryo assessment, pregnancy, time-lapse

Outcome measures

Primary outcome

Primary Objective: To compare the rate of clinical pregnancy at approximately 5-8 weeks gestational age for the Day 3 embryo transfers that used Eeva predictions with morphology grading to that for Day 3 embryo transfers using morphology grading only (from a matched concurrent control group at each clinical site comprised of year 2011 through the date the last subject is enrolled in the Eeva Test Group patients).

Secondary outcome

Secondary Objective(s): To compare the following outcomes from the Eeva test group to the matched control group.

• Implantation rate (# of implanted embryos out of # of total embryos transferred)

• Ongoing pregnancy rate (gestational week 10-12)

• Multiple pregnancy rate

• Spontaneous miscarriage rate

Study description

Background summary

Eeva technology was designed to provide objective information about the embryo*s potential for development and ensure accurate, consistent embryo assessments for the embryologists prior to embryo transfer. Based on the results of the Eeva System study, Eeva is safe, performs according to its specifications, and shows clinical benefit in accordance with its intended use. The capability of Eeva to predict which embryo will develop into a blastocyst may result in fewer implantation failures and fewer unproductive IVF cycles. The next logical step is to gather data to compare the rate of clinical pregnancy for the Day 3 embryo transfers that used the Eeva blastocyst prediction as an adjunct to traditional morphology grading (test group), to that for the Day 3 embryo transfers that used morphology grading only (matched control group).

Study objective

The main objective is to compare the rate of clinical pregnancy at approximately 5-8 weeks gestational age for the Day 3 embryo transfers that used Eeva predictions with morphology grading to that for Day 3 embryo transfers using morphology grading only (from a matched concurrent control group at each clinical site comprised of year 2011 through the date the last subject is enrolled in the Eeva Test Group patients).

Study design

This is a prospective, observational, single arm, nonrandomized, multicenter clinical study with a matched concurrent case control data (year 2011 through the date the last subject is enrolled in the Eeva Test Group patients) from each clinical site.

Intervention

For all included patients, an Eeva prediction will be used in addition to the standard morphology to select the embryo for transfer.

Study burden and risks

The potential for risks is very low. The risks identified through the risk management process which may be associated with the Eeva System were not observed in the first clinical investigation, and no subject needed additional medical procedures due to use of the Eeva System to image her embryos.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

•Women undergoing fresh in vitro fertilization treatment using their own eggs or donor eggs.
•IVF cycle attempts are <= 3.
•Planned Day 3 embryo transfer.
•Egg age >= 18 and <= 40 years.
•At least 5 normally fertilized eggs (2PN).
•All 2PN embryos must be imaged by Eeva.
•Normal uterine cavity as evaluated by standard methods.
•Fertilization using only ejaculated sperm (fresh or frozen)
•Willing to comply with study protocol and procedures.
•Willing to provide written informed consent.

Exclusion criteria

•Patients with surgically removed sperm.
•Patients with planned preimplantation genetic diagnosis or preimplantation genetic screening.
•Patients with a planned *freeze all* cycle.
•Patients with concurrent participation in another clinical study.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-02-2013
Enrollment:	220
Type:	Actual

Medical products/devices used

Generic name:	Eeva (Early Embryo Viability Assessment)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-12-2012
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	10-12-2013
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
ClinicalTrials.gov	NCT01671644
CCMO	NL41843.000.12