A multicentre randomized controlled trial on the efficacy of laser assisted hatching in poor prognosis patients undergoing IVF or ICSI

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

Summary

ID

NL-OMON29700

Source
ToetsingOnline

Brief title
The AHA-trial

Condition

- Other condition

Synonym
subfertility - assisted reproductive technologies

Health condition

onvervulde kinderwens

Research involving

Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: gedeeltelijk door zorgverzekeraar Zilveren Kruis Achmea in het kader van zorgvernieuwing

Intervention

Keyword: Assisted hatching, Fertility treatment, ICSI, IVF

Outcome measures

Primary outcome

The primary study parameter is the live birth rate per couple included

following one IVF/ICSI treatment, including pregnancies from cryopreserved and

thawed embryos transferred before the end of the inclusion period (cumulative

live birth rate).

Secondary outcome

Secondary study parameters are:

- the pregnancy rate (as defined by a positive pregnancy test 14 days following

embryo transfer) per treatment cycle started, per oocyte retrieval and per

embryo transfer, including pregnancies from cryopreserved and thawed embryos

transferred before the end of the inclusion period;

- the ongoing pregnancy rate (a vital pregnancy 10 weeks after embryo transfer)

per treatment cycle started, per oocyte retrieval and per embryo transfer,

including pregnancies from cryopreserved and thawed embryos transferred before

the end of the inclusion period;

- the implantation rate per embryo transferred;

- the multiple pregnancy rate;

- the monozygotic twinning rate;

- the percentage of major and minor malformations in the children born as

assessed at birth.

Study description

Background summary

Hatching is the process in which the embryo is extruded from the zona pellucida which surrounds the oocyte and the embryo just before implantation in the endometrium. Artificial reproductive technologies such as IVF and ICSI have been brought in relation to alterations in the zona pellucida, thereby hampering hatching and diminishing pregnancy rates.
Assisted hatching is a laboratory technique which might overcome this negative influence by breaching, dissolving of weakening the zona pellucida. Assisted hatching is applied in many centres worldwide, albeit not in The Netherlands. There is scientific evidence that assisted hatching might especially be effective in poor prognosis patients, however the evidence regarding the efficacy of assisted hatching expressed as live birth rate is only weak.
The goal of this study is to provide evidence whether assisted hatching positively influences the live birth rate in poor prognosis patients undergoing IVF or ICSI.

Study objective

The main objective is to determine if assisted hatching improves the live birth rate in poor prognosis patients. The secondary objective is to gather information on the safety of assisted hatching as determined by the number of congenital abnormalities diagnosed perinatally in comparison with the control group.

Study design

Double blind multicentre randomized controlled intervention study.

Intervention

Patients will be randomized between no intervention and the intervention laser assisted hatching on the embryos transferred. In the latter case in one focus plane, one eighth of the the zona pellucida will be removed.

Study burden and risks

The burden in the patients allocated to assisted hatching is comparable to that of control patients, i.e. both groups receive a standard IVF or ICSI treatment. In addition, all patients with an ongoing pregnancy will receive a questionnaire on the perinatal outcome of the pregnancy. Embryos in the intervention group will undergo laser assisted hatching before transfer, possibly leading to improved implantation rates. The benefit for the patients in the intervention group is possibly an increased live birth rate. The major risk for the embryos and patients is an increased monozygotic twinning rate after assisted hatching.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with an indication for an IVF/ICSI treatment which meet the following criterium:
- Repeated implantation failure.

Exclusion criteria

1. No indication for IVF/ICSI treatment or with contraindications for IVF/ICSI treatment;
2. Not able or willing to provide informed consent;
3. Unable to speak or read the Dutch language;
4. Medical contraindication for pregnancy or childbirth;
5. Positive serology for Hepatitis B (in the case of ICSI) or HIV (in the case of IVF and ICSI).

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-11-2012
Enrollment:	588
Type:	Actual

Medical products/devices used

Generic name:	ZILOS-tk (Zona Infrared Laser Optical System)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-10-2012
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	17-12-2012
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	30-08-2016
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

ID: 26138
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL36590.000.12