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

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Laser assisted hatching increases the live birth rate in poor prognosis patients.

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

Samenvatting

ID

NL-OMON26138

Bron
NTR

Verkorte titel
The AHA trial

Aandoening

Assisted reproductive technologies
IVF / ICSI

Geassisteerde voorplanting
IVF / ICSI

Ondersteuning

Primaire sponsor: Isala klinieken Zwolle
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

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.

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:

Multicentre randomized controlled intervention study.

Study population:

Poor prognosis patients undergoing IVF or ICSI. Poor prognosis is defined by: Couples with at least two previous IVF or ICSI attempts not resulting in pregnancy (repeated implantation failure).

Intervention:

Patients will be randomized between no intervention and the intervention laser assisted hatching on the embryos transferred.

Main study parameters/endpoints:

The main study parameter is the difference in live birth rate between the control and the assisted hatching group. Besides this, other study parameters include the (ongoing) pregnancy rate, the implantation rate, monozygotic twinning rate and the number of congenital abnormalities diagnosed perinatally.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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.

Doel van het onderzoek

Laser assisted hatching increases the live birth rate in poor prognosis patients.

Onderzoeksopzet

1. The live birth rate: Assessed at birth;

2. The pregnancy rate: 14 days following embryo transfer;

3. The ongoing pregnancy rate: 10 weeks after embryo transfer;

4. The implantation rate: 10 weeks after embryo transfer;

5. The multiple pregnancy rate: 10 weeks after embryo transfer;

6. The monozygotic twinning rate: 10 weeks after embryo transfer;

7. The percentage of major and minor malformations in the children born: assessed at birth.

Onderzoeksproduct en/of interventie

In the intervention group, the embryos to be transferred will undergo laser assisted hatching. One eighth of the ZP will be completely breached using the laser. Laser pulse duration should not exceed 400 µs per pulse at a maximum power of 100%, corresponding to 285mW output peak power in clinical mode. If the isotherm rings are used, the rings corresponding to 60oC and higher should not contact the adjacent blastomeres. Preferably, a part of the ZP is selected with underneath a large area of perivitelline space or in the vicinity of an area with extensive fragmentation.

In the control group, the embryos to be transferred will not undergo laser.

Contactpersonen

Publiek

Fertility Centre Isala
Isala klinieken
P.O.Bos 10400
M.H.J.M. Curfs
Zwolle 8000 GK
The Netherlands
+31 (0)38 4245888

Wetenschappelijk

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Zwolle 8000 GK
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Repeated implantation failure.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Couples with no indication for IVF/ICSI treatment or with contraindications for IVF/ICSI treatment such as cardiovascular-pulmonary disease, severe diabetes, bleeding disorders, immunodeficiency and morbid obesity (i.e. a BMI of over 35);

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). (conform: Standpunt inzake screening op infectieziekten bij kunstmatig geassisteerde voortplanting, www.embryologen.nl).

Onderzoeksopzet

Opzet

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

Deelname

Nederland
Status: Werving gestopt

(Verwachte) startdatum:	28-11-2012
Aantal proefpersonen:	588
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	06-04-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 29700
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3235
NTR-old	NTR3387
CCMO	NL36590.000.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON29700

Resultaten

Samenvatting resultaten
N/A