Effect of lowering the transition metals and ammonium concentration in human culture media on the quality of the human embryos.

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Removal of transition metals and ammonium from human IVF culture system by an inorganic ion exchanger in the form of a zeolite block packed in gelatine will improve the health and quality of cultured human embryos.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29264

Bron
NTR

Verkorte titel
Tramm-ex

Aandoening

In vitro fertilisation, human embryo, embryo culture, ammonium, transition metals

Ondersteuning

Primaire sponsor: GIFT, ZOL, Genk, Belgium Private infertility center in a university-affiliated teaching hospital and Newcastle Fertility Centre at LIFE, Newcastle, UK, University affiliated Center.
M. Nijs, GIFT, Genk and Herbert M, LIFE, Newcastle.
Overige ondersteuning: Tramm-ex will be provided by Birr Biosciences

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Embryo quality (quality and cell number in embryo) and clinical pregnancy rate.

Toelichting onderzoek

Achtergrond van het onderzoek

The presence of ammonium in human embryo culture medium has a negative effect on embryo physiology and biochemistry. Ammonium concentration will increase due to spontaneous degradation of amino acids as well as by the metabolism of the embryo. Traces of transition metals like copper or iron can have a detrimental effect on embryo development as well. Removal of these embryo-toxic elements during embryo culture could improve the health and quality of the human embryo.
Tramm-ex is a zeolite block with cross linked gelatin and is an inorganic ion exchanger. Laboratory test have shown that Tramm-ex removes 50% of the ammonium content as well as a factor 100.000 of the transition metals from culture medium. Zeolite has no negative effect on mouse embryo development. The sperm survival test did not identify the Tramm-ex blocks as embryotoxic. In this prospective randomised study, human embryos will be cultured with and without Tramm-ex. Embryo quality and health as well as clinical pregnancy rates will be evaluated.

Doel van het onderzoek

Removal of transition metals and ammonium from human IVF culture system by an inorganic ion exchanger in the form of a zeolite block packed in gelatine will improve the health and quality of cultured human embryos.

Onderzoeksopzet

Embryo quality (during the 5-day embryo culture) and clinical pregnancy rate (12 days and 6 weeks after embryo transfer).

Onderzoeksproduct en/of interventie

Embryo culture will be performed with or without the inorganic ionexchanger Tramm-ex. The randomisation is performed by ‘the research randomizer’ on 100 consecutive patients undergoing IVF/ICSI treatment in each centre. Each centre receives a list for randomisation. Randomisation is performed at the time of check for fertilisation. Embryo scoring and

selection for transfer and/or cryopreservation is done according to standard methods. Single embryo transfer from either culture system is done on day 3, 4 or 5.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients entering the IVF/ICSI program.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. ICSI cases for preimplantation genetic diagnosis;

2. ICSI cases with testicular spermatozoa.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2009
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL1511
NTR-old	NTR1581

Register	ID
Ander register	intern : GIFTNFC2009-1
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A