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Comparison of two ready-to-use systems specially designed for physiological intracytoplasmic sperm injection (ICSI): PICSI® versus Sperm Slow™, a prospective randomised trial

Submission date
24/08/2010

Recruitment status
No longer recruiting

Registration date
11/10/2010

Overall study status
Completed

Last Edited
18/12/2020

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Study information

Scientific Title

Comparison of two ready-to-use systems specially designed for sperm-hyaluronic acid (HA) binding selection before intracytoplasmic sperm injection (physiological ICSI): PICSI® versus Sperm Slow™, a prospective randomised trial

Study objectives
The objective of this study is to evaluate the role of hyaluronic acid (HA) for sperm selection prior to intracytoplasmic sperm injection (ICSI) comparing two ready-to-use systems specially designed for sperm-HA binding selection: a plastic culture dish with microdots of HA hydrogel attached to the bottom interior of the dish (PICSI® Sperm Selection Device, MidAtlantic Diagnostic) or a viscous medium containing HA (Sperm Slow™, MediCult). These systems, in which the spermatozoa are selected for their capacity to bind to HA (HA-ICSI), allow the execution of a more "physiological" ICSI than conventional PVP-ICSI.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Medical Ethics Committee of GynePro Medical Center approved in December 2007

Study design
Single centre prospective randomised study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Intracytoplasmic sperm injection (ICSI)

Interventions
100 ICSI treatments randomly carried out with PICSI® Sperm Selection Device or with Sperm Slow™ for sperm selection. Randomisation process conducted with sealed envelopes, assigning 50 subjects to each treatment group.

Controlled ovarian stimulation with gonadotropin-releasing hormone analogs in combination with a graded gonadotropin administration. Oocyte retrieval performed 35 hours after ovulation induction with either 5,000 or 10,000 IU of human chorionic gonadotropin (hCG). Oocytes culture at 37°C in an atmosphere of 6% CO2. Complete removal of cumulus mass and corona cells by enzymatic digestion of recombinant hyaluronidase (SynVitro® Cumulase® MediCult) and by gentle mechanical aspiration with plastic pipettes (Stripper Tips® MidAtlantic Diagnostic).

Assessment of the nuclear maturation stage of the denuded oocytes. Strict selection of the metaphase II oocytes (MII) by morphological features (zona pellucida thickness, perivitelline space size, oocyte shape, cytoplasm colour and granularity, presence of vacuoles and first polar body morphology) under an inverted microscope with Hoffman modulation contrast.

Classification of "high quality oocytes": colourless and of regular shape, with regular zona pellucida and small perivitelline space without debris, homogeneous cytoplasm and no vacuoles or granulations.

Insemination by ICSI of the best available MII oocytes, in accordance with the Italian law regulating Assisted Reproductive Technology (cryopreservation of the supernumerary MII oocytes reaching the "high quality" standards).

PICSI® Sperm Selection Device procedure as described in www.midatlanticdiagnostics.com.

Sperm Slow™ ICSI procedure:
Spermatozoa must first be treated with a two-layer density gradient system or via Swim-Up. Thus, on a Petri dish, a 2 µL droplet with suspension of treated spermatozoa is connected with a pipette tip to a 5 µL droplet fresh culture medium (Sperm Preparation Medium, MediCult). Simultaneously, A 5 µL droplet of HA-containing medium (Sperm Slow™, MediCult) is connected with a pipette tip to the 5 µL droplet fresh culture medium. The spermatozoa on this Petri dish are incubated for 15 min at 37°C under oil (Liquid Paraffin, MediCult). Spermatozoa bound to HA in the junction zone of the 2 droplets can be selected and easily detached by injecting pipette (ICSI Micropipets, Humagen Fertility Diagnostics) and subsequently injected into oocytes.

Controlled ovarian stimulation duration: from 12 to 20 days
Oocyte recovery, ICSI, embryo culture and embryo transfer duration: from 3 to 5 days

The follow up will be completed at confirmation of clinical pregnancy by ultrasound check of gestational chamber, 30 days after the embryo transfer.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Oocyte fertilisation rate, measured 15 - 22 hours after oocyte insemination
2. Embryo cleavage rate, measured at day of embryo transfer (2, 3 or 5 days after oocyte insemination)
3. Top-quality embryo rate, measured at day of embryo transfer (2, 3 or 5 days after oocyte insemination)
4. Pregnancy rate, measured 30 days after the embryo transfer
5. Implantation rate, measured 30 days after the embryo transfer

Key secondary outcome(s))
Duration of ICSI procedure, measured at time of oocyte insemination

Completion date
01/03/2011

Eligibility

Key inclusion criteria
1. Infertile women not older than 41 years undergoing ICSI treatment at GynePro Medical Center
2. Semen parameters of the male partner:

2.1. Presence of ejaculate motile spermatozoa with total sperm number greater than or equal to 1,000,000
2.2. Sperm motility greater than or equal to 5%

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
100

Key exclusion criteria
1. Women older than 41 years old
2. Patients with male partners with testicular spermatozoa or severe oligoastenoteratozoospermia (total sperm number less than 1,000,000 and sperm motility less than 5%)

Date of first enrolment
01/09/2010

Date of final enrolment
01/03/2011

Locations

Countries of recruitment
Italy

Study participating centre
GynePro Medical Centers
Bologna
Italy
40137

Sponsor information

Organisation

GynePro Medical Centers (Italy)

ROR
https://ror.org/03segdh23

Funder(s)

Funder type
Industry

Funder Name
GynePro Medical Centers (Italy)

Funder Name
MidAtlantic Diagnostic (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2012	18/12/2020	Yes	No