

QUALIMORPH - Embryo quality evaluation in Intra Cytoplasmic Sperm Injection (ICSI) cycles with Fertimorph system

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Last update : 01/01/2020 | Version : 1 | ID : 197

General

Identification

Detailed name Embryo quality evaluation in Intra Cytoplasmic Sperm Injection (ICSI) cycles with Fertimorph system

Sign or acronym QUALIMORPH

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL (22/12/2009)

General Aspects

Medical area Biology

Health determinants Iatrogenic

Others (details) Infertility

Keywords In Vitro Fertilization (IVF), FertiMORPH system, embryo quality, Intra Cytoplasmic Sperm Injection ICSI

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Collaborations

Funding

Funding status	Private
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Details	Ferring SAS
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Governance of the database

Sponsor(s) or organisation(s) responsible	Ferring SAS
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Organisation status	Private
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Additional contact

Main features

Type of database

Type of database	Study databases
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Study databases (details)	Not-repeated cross-sectional studies (except case control studies)
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Database recruitment is carried out by an intermediary	A selection of health institutions and services
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Database recruitment is made on the basis of:	Another treatment or procedure
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Database recruitment is carried out as part of an interventional study	No
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Database objective

Main objective	Evaluate the concordance between the embryo quality appreciated by the biologist according to his normal technique and according to the Fertimorph system
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Inclusion criteria	Embryos coming from couples having the following characteristics: -Criteria linked to the woman: woman with normal
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response, all infertility etiologies, aged up to 36 years, maximum of one prior assisted reproduction technique (ART) cycle, current ART cycle with ICSI with ejaculated or frozen sperm, normal ovarian reserve (evaluated via hormone assays and where applicable by an antral follicle count), with a normal uterus and without hydrosalpinx.
-Criteria linked to the spouse: diagnosed male infertility, where applicable normal male karyotype,
-Criteria linked to the studied attempt: at least 5 mature (MII) oocytes retrieved, maximum of two embryos transferred.

Population type

Age
Adulthood (19 to 24 years)
Adulthood (25 to 44 years)

Population covered
Sick population

Gender
Woman

Geography area
National

Detail of the geography area
Multi-center study - 7 centers in France: Besançon, Grenoble, Lille, Montpellier, Strasbourg, Toulouse, Brest

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)
2010

Date of last collection (YYYY or MM/YYYY)
2010

Size of the database

Size of the database (number of individuals)
< 500 individuals

Details of the number of individuals
130

Data

Database activity
Data collection completed

Type of data collected
Clinical data
Biological data

Clinical data (detail)	Direct physical measures Medical registration
Biological data (detail)	Number and quality of the ovocytes, fertilization parameters, number and quality of the embryos
Presence of a biobank	No
Health parameters studied	Others
Other (detail)	Biological parameters: embryo quality and development

Procedures

Participant monitoring	No
Links to administrative sources	No

Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)	Under discussion
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only