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Efficacy of indomethacin in in-vitro fertilisation treatment in the modified natural cycle

Submission date 07/03/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/03/2007	**Overall study status** Completed	
Last Edited 26/08/2021	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL656 (NTR907)

Study information

Scientific Title
Efficacy of indomethacin in in-vitro fertilisation treatment in the modified natural cycle

Study objectives

Indomethacin is known to be a strong inhibitor of ovulation in the spontaneous menstrual cycle. Therefore we assume that the use of indomethacin prior to follicle aspiration in In-Vitro Fertilisation-treatment in the Modified Natural Cycle (IVF-MNC) significantly decreases the number of patients with one or more premature ovulations compared to placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local medical ethics committee (Medisch Ethische Toetsingscommissie UMC Groningen) on the 24th June 2005 (ref: 2005/074).

Study design
Randomised, placebo controlled, parallel group, double blinded trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
In-vitro fertilisation-treatment in the modified natural cycle, IVF in the natural cycle

Interventions
Use of indomethacin (Indocid®) 50 mg versus placebo during IVF-treatment in the modified natural cycle.
Dosage scheme: three times a day, starting on the day of ovulation triggering and ending on the morning of the follicle aspiration (total of seven capsules per cycle).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Indomethacin (Indocid®)

Primary outcome(s)
Number/percentage of patients per study group that have one or more ovulations prior to follicle aspiration.

Key secondary outcome(s))
Number/percentage of patients per study group that achieve an on-going pregnancy (defined as an intact intra-uterine pregnancy at 12 weeks gestation)

Completion date
01/11/2007

Eligibility

Key inclusion criteria
1. Indication for IVF or Intracytoplasmic Sperm Injection (ICSI) treatment
2. Age 18 up to 37 years
3. Ovulatory cycle of 26 to 35 days

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Prior IVF or ICSI treatment unless the last treatment was successful
2. Ovarian cysts disabling adequate sonographic assessment of the ovaries
3. Contraindications for indomethacin, such as asthma or prior gastro-intestinal ulcer

Date of first enrolment
05/12/2005

Date of final enrolment
01/11/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Groningen
Groningen
Netherlands
9700 RB

Sponsor information

Organisation
University Medical Centre Groningen (UMCG) (The Netherlands)

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Groningen (UMCG) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration