

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

Submission date 07/03/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 07/03/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 26/08/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Number/percentage of patients per study group that have one or more ovulations prior to follicle aspiration.

Secondary outcome measures

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

Overall study start date

05/12/2005

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

120

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)

Sponsor details

Department of Obstetrics and Gynaecology

Groningen

Netherlands

9700 RB

Sponsor type

Hospital/treatment centre

Website

<http://www.umcg.nl/azg/nl/english/azg/>

ROR

<https://ror.org/03cv38k47>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Medical Centre Groningen (UMCG) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration