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Aspirin in in vitro fertilisation (IVF)

Submission date 04/04/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/04/2006	**Overall study status** Completed	
Last Edited 26/08/2009	**Condition category** Urological and Genital Diseases	

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
NTR610

Study information

Scientific Title
Added 26/08/09: Low dose aspirin in IVF. A prospective, randomised, double blind placebo controlled trial.

Study objectives
By its pharmacological action it is likely that aspirin improves ovarian perfusion, uterine perfusion and reduces endometrial restraint on the implanting embryo. Therefore the hypothesis of this study is that the use of low dose aspirin in IVF improves pregnancy rates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Prospective randomised double blind placebo controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Subfertility

Interventions
Patients undergo regular IVF/ICSI treatment combined with low dose aspirin or placebo.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Ongoing pregnancy rate

Secondary outcome measures
1. Number of follicles
2. Number of oocytes retrieved

Overall study start date
01/06/2002

Completion date
01/08/2007

Eligibility

Key inclusion criteria
1. Patients undergoing IVF or intracytoplasmic sperm injection (ICSI) treatment
2. Age <39 years
3. Cycle day 3 follicle stimulating hormone (FSH) <10 IU/l
4. No contra-indications against the use of low-dose aspirin

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
150

Key exclusion criteria
1. Systemic diseases
2. Hypertension
3. Previous allergic reaction to study medication
4. Previous ovarian hyperstimulation syndrome (OHSS)
5. Untreated endocrinopathies
6. Smoking >5 cigarettes/day
7. Body mass index (BMI) >28

Date of first enrolment
01/06/2002

Date of final enrolment
01/08/2007

Locations

Countries of recruitment
Netherlands

Study participating centre

VU University Medical Center
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
VU University Medical Centre (VUMC) (Netherlands)

Sponsor details
Department of Obstetrics and Gynaecology,
Division of Reproductive Medicine
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
VU University Medical Centre (VUMC) (Netherlands) - Department of Obstetrics and Gynaecology, Division of Reproductive Medicine

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2009		Yes	No