Aspirin in in vitro fertilisation (IVF)

Submission date	Recruitment status No longer recruiting	Prospectively registered	
04/04/2006		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
04/04/2006	Completed	[X] Results	
Last Edited 26/08/2009	Condition category Urological and Genital Diseases	[] Individual participant data	
/n/UX//UU9	- Urological and Genifal Diseases		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 P.O. Box 7057 Amsterdam Netherlands 1007 MB

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 summaryNot 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