ISRCTN23488518 https://doi.org/10.1186/ISRCTN23488518

A randomised controlled trial to compare conception rates for preconceptional folic acid 400 mg daily versus Pregnacare Plus in assisted conception

Submission date 02/07/2007	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/07/2007	**Overall study status** Stopped	
Last Edited 09/02/2009	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr John Nichols

Contact details
60 Manor Way
Onslow Village
Guildford
United Kingdom
GU2 7RR
+44 (0)1483 564967
drjaan@ntlworld.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2007-6

Study information

Scientific Title

Study objectives
1. Micronutrient status influences the outcome of pregnancy and normal micronutrient status is necessary for a normal outcome
2. Micronutrient deficiency may prevent assisted conception, or if conception occurs there may be complications including early pregnancy loss and small-for-dates infant at birth
3. Assisted conception subjects who take ten weeks pre-conceptional Pregnacare Plus will produce more pregnancies that survive to 20 weeks than subjects on folic acid 400 mg in sub-fertile patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 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
Female infertility

Interventions
Randomised controlled trial of folic acid (400 mcg) versus Pregnacare Plus (contains folic acid 400 mcg and 17 other micronutrients) given for 10 weeks prior to assisted conception and follow-up to 20 weeks in those that become pregnant. Subjects will also be monitored for nutritional status.

Intervention Type

Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Preconceptional folic acid, Pregnacare Plus

Primary outcome measure
Survival of assisted conception pregnancy to 20 weeks, or failure to conceive and failure of pregnancy to survive to 20 weeks.

Secondary outcome measures
1. Length of pregnancy
2. Birth weight (expressed as percentile birth weight in relation to length of pregnancy)
3. Abdominal circumference
4. Head circumference

Overall study start date
01/11/2007

Completion date
01/11/2009

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Sub-fertile subjects scheduled for In Vitro Fertilisation (IVF) or Intra-Uterine Insemination (IUI)
2. Aged less than 35 years
3. Infertility lasting for greater than six months

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
140

Key exclusion criteria

1. Aged greater than 35 years
2. General medical conditions that make a patient unsuitable for assisted conception (i.e. morbid obesity)
3. Women whose understanding of English is insufficient to consent to participation

Date of first enrolment
01/11/2007

Date of final enrolment
01/11/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
60 Manor Way
Guildford
United Kingdom
GU2 7RR

Sponsor information

Organisation
The Royal Surrey County Hospital NHS Trust (UK)

Sponsor details
Egerton Road
Guildford, Surrey
England
United Kingdom
GU2 7RR
+44 (0)1483 571122
mary.tourette@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.royalsurrey.nhs.uk/Homepage.aspx

ROR
https://ror.org/050bd8661

Funder(s)

Funder type
Government

Funder Name
The National Institute of Health Research (NIHR) (UK) - Research for Innovation, Speculation and Creativity (RISC) scheme (awaiting outcome of application for funding).

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