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

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

#### 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

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 subfertile 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

#### 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