

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 10/07/2007	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 09/02/2009	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

Protocol serial number

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-conceptual 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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

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

Sponsor information

Organisation

The Royal Surrey County Hospital NHS Trust (UK)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration