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Effect of maternal vitamin C supplementation on plasma vitamin C levels in preterm infants during the early neonatal period

Submission date 12/09/2003	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Stopped	
Last Edited 15/07/2009	**Condition category** Pregnancy and Childbirth	

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
N0217117009

Study information

Scientific Title

Study objectives
To determine whether maternal vitamin C supplementation prior to preterm delivery results in:
1. Higher maternal plasma vitamin C level at the time of delivery
2. Higher vitamin C levels in preterm infants at birth and at 5 days postnatal age

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double blinded prospective randomised placebo-controlled study

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Neonatal Diseases: Vitamin supplementation

Interventions
Vitamin C vs placebo

Added 15/07/09: the trial never started.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamin C

Primary outcome(s)
Neonatal plasma vitamin C level after delivery and at 5 days postnatal age

Key secondary outcome(s))
Not provided at time of registration

Completion date
24/09/2005

Reason abandoned (if study stopped)
Lack of funding/sponsorship + Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
Pregnant women admitted to Hope Hospital antenatally who are at high risk of premature delivery before 35 weeks gestation.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Does not match inclusion critera.

Date of first enrolment
24/09/2002

Date of final enrolment
24/09/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Neonatal ICU
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Salford Royal Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration