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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

Contact name
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Contact details
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M6 8HD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
Neonatal plasma vitamin C level after delivery and at 5 days postnatal age

Secondary outcome measures
Not provided at time of registration

Overall study start date
24/09/2002

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

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
Neonatal ICU
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Salford Royal Hospitals NHS Trust (UK)

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