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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr PA Clarke

Contact details

Neonatal ICU Hope Hospital Stott Lane Salford United Kingdom M6 8HD

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