

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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 15/07/2009	<b>Condition category</b> Pregnancy and Childbirth	<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

### Contact name

Dr PA Clarke

### Contact details

Neonatal ICU  
Hope Hospital  
Stott Lane  
Salford  
United Kingdom  
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 criteria.

**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